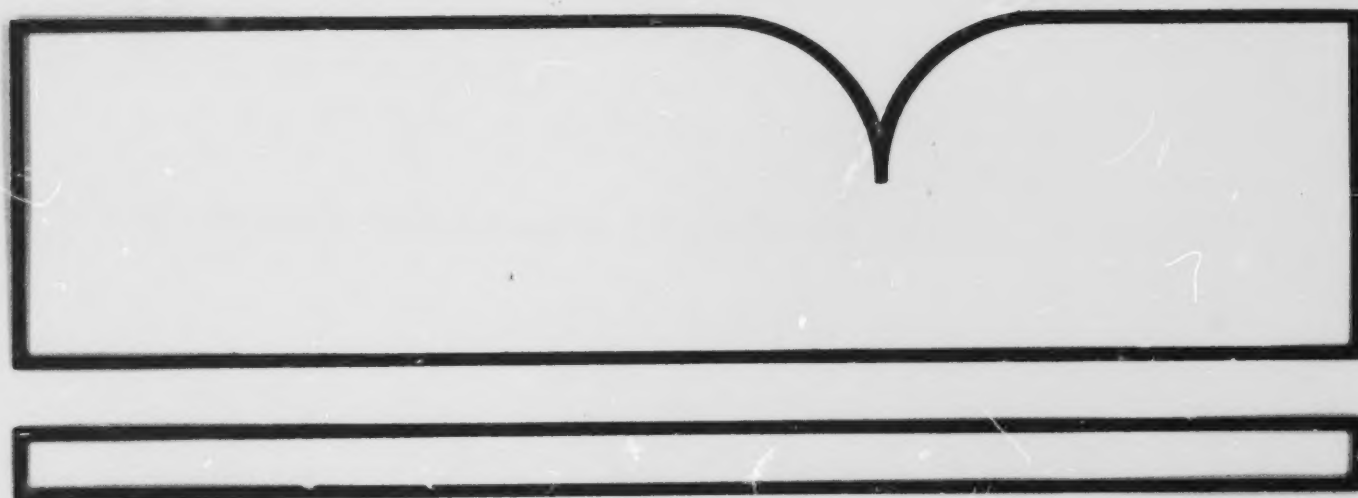


PB90-130725

Guidance for the Reregistration of Pesticide Products
Containing Ethion as the Active Ingredient

(U.S.) Environmental Protection Agency, Washington, DC

29 Sep 89



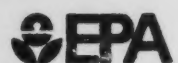
U.S. Department of Commerce
National Technical Information Service

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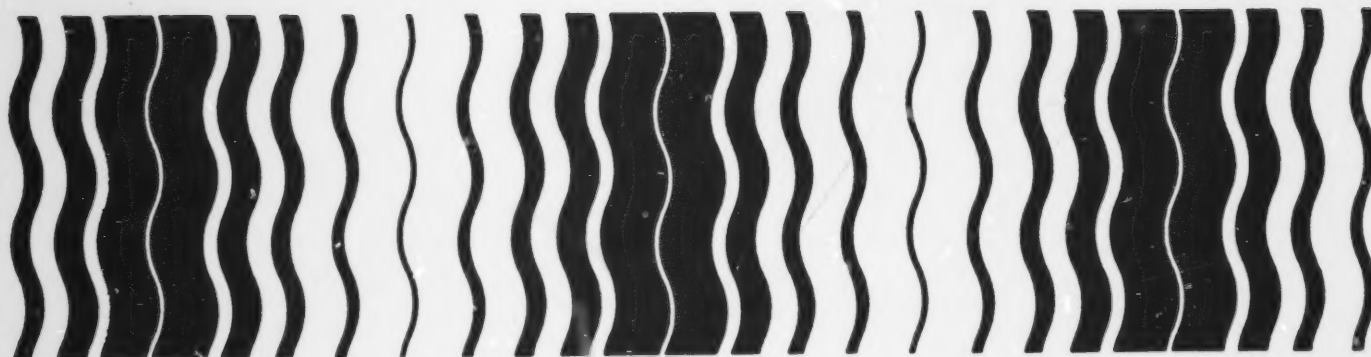
United States
Environmental Protection
Agency

Pesticides and
Toxic Substances
(H-7501C)

540/RS-90-074



Registration Standard For Pesticide Products Containing Ethion As The Active Ingredient



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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
ETHION
AS THE ACTIVE INGREDIENT

OPP Chemical Number: 058401

GS 0090

CAS (DOCKET) NUMBER : 563-12-2

September 29, 1989

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob With Husk Removed
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.

GLOSSARY OF TERMS AND ABBREVIATIONS (continued)

MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

I. INTRODUCTION

This document is a revised Registration Standard ethion. In its original Standard, issued in 1982 the Agency summarized the available data supporting the registration of the pesticide and its assessment of those data to determine whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Standard also set out labeling requirements that the Agency believed were necessary to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has since reviewed the additional data and has updated and revised its scientific and regulatory conclusions concerning the pesticide in light of expanded data requirements promulgated in 1984 as 40 CFR Part 158. The Registration Standard contains the Agency's updated scientific assessment¹ of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard.

Based on the new data, the Agency has also reviewed the labeling requirements for the pesticide and is requiring label revisions.

This revised Registration Standard supersedes the original Registration Standard in its entirety.

This document contains the following sections:

- ° Section II describes the particular pesticide(s) covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.

¹The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506c), Office of Pesticide Programs, EPA, Washington, D.C. 20460.

° Section III sets out the Agency's scientific assessment of the health risks and environmental characteristics and effects of the chemical, updated based on data submitted to the Agency under the original Registration Standard.

° Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions. Section IV also describes the labeling statements required for products containing the chemical. These are divided into statements for manufacturing use products and statements for end use products.

° Sections V, VI, VII, VIII and IX describe what products are subject to the data and labeling requirements set out in this Registration Standard, and what is required of registrants to comply with the requirements.

° Appendix I contains a series of tables setting out data requirements for the chemical. The tables identify which requirements have been satisfied, as well as those for which gaps remain. A Guide to Tables introduces the tables.

° Appendix II is a series of labeling information sheets, setting out general labeling information that must be placed on labeling.

° Appendix III is a bibliography of the data evaluated by the Agency in its assessment. A Guide to Bibliography explains how to read and use the Bibliography.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

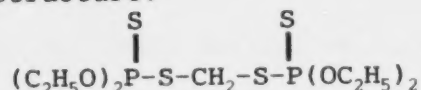
A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common Name: Ethion

Generic (Chemical) Name: O,O,O',O'-Tetraethyl S, S'-methylene bis (phosphorodithioate)

Chemical Structure:



Chemical Family: Organothiophosphate member of the Organophosphate family.

B. OTHER IDENTIFYING CHARACTERISTICS AND CODES

CAS Registry Number: 563-12-2

EPA Pesticide Chemical Code (Shaughnessy Number):
058401

Empirical Formula: $\text{C}_9\text{H}_{22}\text{O}_4\text{P}_2\text{S}_4$

Molecular Weight: 384.5

Physical/Chemical Characteristics of the Technical Grade:

EPA Reg No. 279-2280
4787-10
2749-293 (suspended 7/4/85)

Color: colorless to light brown or pale yellow.

Physical state: liquid at room temperature.

Odor: mild dithiophosphate

Melting point: -12° to -15°C

Boiling point: $164-165^\circ\text{C}$ at 0.3 mm Hg.

Specific gravity: 1.215 - 1.230 at 20°C

Physical/Chemical Characteristics of the Technical
Grade: (continued).

Solubility: Practically insoluble in water; soluble in most organic solvents.

Vapor pressure: 1.5×10^{-6} mm Hg at 25°C.

Dissociation constant: Not applicable; TGAI does not disperse in water.

Octanol/water partition coefficient: 10,000 [GC with FPD detector].

pH: 5.1 in an equal volume of distilled water.

Storage stability: 95% of ethion remained unchanged during one year of storage at 25°C. There was <2% deterioration in three years of storage under the same conditions. Recommended shelf life is two years. Do not store below 20°F to avoid crystal formation.

Corrosion: Ethion does not corrode stainless steel or aluminum.

C. USE PROFILE

Type of insecticide: non-systemic insecticide

Year of Initial Registration: 1965

Registered Uses:

Terrestrial Food Crop Use: Alfalfa (seed crop), almonds, apples, apricots, beans, cherries, chestnuts, corn (field), cotton, cucumbers, eggplants, filberts, grapefruit, grapes, lemons, limes, melons, nectarines, onions (dry & green), oranges, peaches, pears, pecans, peppers, pimentos, plums, prunes, sorghum (grain & forage), sorghum (seed crop), squash (summer), strawberries, tangelos, tangerines, tomatoes, and walnuts.

Registered Uses: (continued)

Terrestrial Non-food Crops: Bermudagrass, Junipers, ornamental evergreens, pine trees, lawns, ornamental turf, and ornamental plants.

Greenhouse Non-food Crops: Ornamental plants.

Domestic Outdoor Uses: Domestic dwellings, and lawns.

Pests Controlled: Leaf-feeding insects, mites, and scales.

Methods of Application: Ground and aerial foliar applications, furrow treatments by ground equipment, and seed treatment.

Annual Usage: 1.2 to 1.5 million pounds of active ingredient are used in the United States.

Predominant Usage: Citrus accounts for 86% to 89% of the total pounds of ethion used in the United States. The remaining 11% to 14% is applied to cotton and a variety of fruit trees, nut trees, and vegetables. Approximately 55% to 70% of all domestically produced citrus fruits are treated with ethion. Less than 2% of the domestic cotton acreage, and fewer than 10% of the fruit (other than citrus), vegetable and nut acreage is treated with ethion.

Mode of Insecticidal Activity: Toxic action is exerted by inhibiting enzymes of the nervous system through inhibition of cholinesterase.

Formulations: Emulsifiable solution: 500g/l
Wettable powder: 25%
Dusts: 2%, 3%, and 4%
Emulsifiable concentrates: 4 and 8 lbs/gal
Granules: 5% and 10%

U.S. and Foreign Producers and Manufacturers:

Cheminova (Denmark)
 FMC Agricultural Chemical Group (US)
 M/S Pesticides (India)
 Rhone-Poulenc Agrochemie (France)
 Sintesul S.A. (Brazil)
 Volrho (India)

Table 1 - Compilation of Ethion Registrations

	<u>Federal</u>		<u>SLN</u>	<u>Total</u>
	Single active ingredient	Multiple active ingredient		
Technical	3	0	0	3
Dust	1	1	0	2
Granular	4	0	2	6
Wettable Powder	6	1	0	7
Emulsifiable concentrate	5	28	7	40
Soluble				
Concentrate Liquid	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Total	19	30	9	58

III. AGENCY FINDINGS

A. Summary of Ethion Data Base

The Agency issued a Registration Standard for ethion in 1982. This Registration Standard required that certain data be submitted to the Agency. As a result, the status of the ethion data base is listed below. This information is presented in summary form; a discussion of the data is presented in the remainder of this section and specific requirements are detailed in the data tables in Appendix I of this document:

1. Toxicology

The following toxicological data requirements are satisfied: acute toxicity, chronic toxicity with the exception of a non-rodent chronic feeding study, oncogenicity, teratogenicity, and reproduction. The requirement for a 90-day non-rodent subchronic feeding study has been satisfied. Because an acceptable chronic rodent feeding study is available, the Agency has determined that the requirement for a subchronic rodent feeding study is waived. Since an acute neurotoxicity did not show neurotoxic effects, a 90-day delayed neurotoxic study is also waived. The requirement for a 21-day dermal toxicity and 90-day inhalation toxicity studies are not necessary under the registered use patterns. The requirement for general metabolism studies is reserved. Three metabolism studies are currently under review by the Agency. The registrant will be notified if additional studies are required. The data requirements for mutagenicity are partially satisfied, a gene mutation study was reviewed and determined to be acceptable. Additional mutagenicity testing is required for chromosomal aberration and other mechanisms of mutagenicity.

2. Residue Chemistry

Data submitted in response to the 1982 Registration Standard showed that additional plant and animal metabolism studies, storage stability studies, residue studies in poultry meat, milk, and eggs, and residue reduction studies in food crops are required to allow a complete dietary exposure assessment.

3. Environmental Effects

The 1982 Ethion Registration Standard required the following environmental fate studies: hydrolysis, photodegradation in water and soil, aerobic and anaerobic soil metabolism, leaching field dissipation (terrestrial) and fish bioaccumulation (lab). These data were submitted and reviewed. The only data requirements that have been satisfied are aerobic soil metabolism and fish accumulation. The hydrolysis data requirement has been partially satisfied and additional hydrolysis studies are required. The remaining environmental fate data are outstanding: photodegradation (water, soil, and air), anaerobic soil metabolism, mobility (leaching and adsorption, and volatility), dissipation (soil), and accumulation (rotational crops).

4. Ecological Effects

The 1982 Registration Standard for ethion required the submission of two studies relating to ecological effects; acute avian oral toxicity and acute toxicity to estuarine and marine organisms. These studies were reviewed and determined to satisfy the data requirements. Based on ethion's persistence, expected residues on avian food, bioaccumulation in fish, and high fish toxicity, additional ecological effects studies are required: fish early life stage and invertebrate life cycle; and avian reproduction.

5. Non-Dietary Exposure

The 1982 Registration Standard required the registrants of ethion products to submit either a full battery of worker protection/reentry studies or adopt the most restrictive reentry intervals imposed by the states. No worker protection/reentry data have been submitted to the Agency for review. The Agency is requiring product labeling relating to worker protection, the most restrictive reentry intervals imposed by the states, and the full battery of worker protection/reentry studies.

B. Health Effects Assessment

Below is an assessment of the human health risks associated with the insecticide ethion based upon the data submitted in response to the 1982 Ethion Registration Standard, and data previously reviewed and determined to be acceptable to support the registration of products containing the active ingredient ethion.

1. Acute Toxicity

There are adequate studies available to assess the acute toxicity of ethion. Technical ethion has a high oral toxicity to mammals, particularly to females. The acute oral LD₅₀ for male rats is 191 mg/kg and 21 mg/kg for female rats. Technical ethion has a moderately high dermal toxicity (LD₅₀ 838 mg/kg) and inhalation toxicity (LC₅₀ of 0.45 mg/kg for females and 2.31 mg/kg for males).

The primary eye irritation study for ethion showed only slight redness of the conjunctivae and this effect cleared within 24 hours. In the primary skin irritation study, technical grade ethion caused slight erythema which cleared within 48 hours. Ethion was judged not to be a skin sensitizer and did not cause delayed neurotoxicity in hens at the dose tested, 2792 mg/kg.

2. Subchronic Toxicity

Sufficient data are available to satisfy the subchronic (21-day) dermal data requirements for ethion that were listed in the 1982 Registration Standard. In the first study reviewed, groups of rabbits (6/sex/dose) received dermal applications of technical ethion at doses 0, 1.0, 3.0, 25, and 250 mg/kg for 21 days. Inhibition of brain cholinesterase activity was seen in all treated males and in the 25 and 250 mg/kg females. Both plasma and red blood cell cholinesterase activities were decreased in 250 mg/kg males and in both the 25 and 250 mg/kg females. Increased incidences of erythema and desquamation at the application sites were found in both male and female rabbits of the 25 and 250 mg/kg groups.

In a study classified as supplemental, groups of New Zealand White Rabbits (6/dose) received dermal applications of technical ethion at doses of 0, 0.1, 0.25, 0.5, 0.8, 1.0, 3.0 and 25 mg/kg for 21 days (6 hrs/day). This study was designed and conducted to determine a NOEL for male rabbits using doses which included those lower than 1.0 mg/kg and similar experimental conditions as the first study which tested doses above 1.0 mg/kg. The brain cholinesterase activity was reduced in animals dosed with 0.5 mg/kg or above, but the decrease did not show a statistical significance. When the results of the two studies were combined and analyzed, significant inhibition was seen in 1.0, 25, and 250 mg/kg animals. Based on these results, the NOEL for the systemic toxicity of ethion was established at 0.8 mg/kg.

A subchronic dog study was reviewed by the Agency and determined to be sufficient in satisfying the requirements set forth in the 1982 Registration Standard for ethion. In this study groups of dogs (4/sex/dose) received ethion orally at dietary concentrations of 0, 0.013, 0.063, 0.625, and 7.5 mg/kg/day for 90 days.

The animals in the 7.5 mg/kg/day dose group showed signs of ataxia, emesis, miosis, and tremors. The male and female dogs of the 7.5 mg/kg/day dose group showed a decrease in body weight and food consumption relative to the controls.

Clinical chemistry indicated that ethion significantly inhibited brain cholinesterase activity in 0.625 and 7.5 mg/kg/day males and females, erythrocyte cholinesterase activity in 7.5 mg/kg males and females, and plasma cholinesterase activity in 0.063, 0.625 and 7.5 mg/kg/day male and female dose groups. The decrease in plasma cholinesterase activity was dose-related.

No compound related histomorphological changes were found in ethion treated animals. Based upon the inhibition of plasma cholinesterase activity, the LEL is 0.063 mg/kg/day and the NOEL of 0.013 mg/kg/day.

No subchronic 90-Day dermal toxicity and subchronic inhalation studies for ethion are available for review. These studies are not required under the present use patterns. Since ethion has not been shown to cause neurotoxicity in an acute delayed neurotoxicity study in hens, a subchronic neurotoxicity study is not required.

3. Chronic Toxicity/Oncogenicity Testing

Chronic Toxicity

A chronic oral toxicity study in rodents was reviewed and determined to be sufficient to satisfy the data requirements specified in the 1982 registration standard. However, a chronic feeding study conducted with dogs was reviewed and determined to be supplemental. This study is inadequate to establish a chronic NOEL and does not satisfy the data requirements for a chronic feeding study in non-rodents. A chronic oral toxicity study in a non-rodent species (preferably dog) is required.

In the chronic oral toxicity study in rodents, groups of Sprague-Dawley Rats (80/sex/dose) were fed ethion at concentrations of 0, 0.1, 0.2, and 2 mg/kg/day. Groups of 20 rats/sex/dose were sacrificed at 6, 12, and 18 months. Decreased serum cholinesterase was observed in the high dose males and females, and no other toxic effects were observed. Based on the cholinesterase inhibition, the systemic NOEL is 0.2 mg/kg/day and the LEL is 2 mg/kg/day.

In the chronic oral toxicity study for non-rodents, groups of beagle dogs (4/sex/dose) were administered ethion at dietary concentrations of 0, 0.05, 0.15, and 0.5 mg/kg/day for 2 years. High dose females (0.5 mg/kg) showed decreased plasma cholinesterase activity. Although no other toxic effects of ethion were observed, the study was considered inadequate to establish a chronic NOEL because of deficiencies.

Oncogenicity

The 1982 Registration Standard for ethion required oncogenicity studies. These data were reviewed by the Agency and determined to be acceptable. These data show that under the conditions of the studies, ethion is not carcinogenic in rats and mice.

In the rat study, groups of Sprague-Dawley rats (80/sex/dose) received diets containing ethion at concentrations of 0, 0.1, 0.2, and 2 mg/kg/day. Interim sacrifices of 10 rats/sex/dose were carried out at 6, 12 and 18 months. Decreased serum cholinesterase was observed in high dose males and females. Tumor incidence was comparable between treated and control animals.

In the mouse study, groups of mice (80/sex/dose) received diets containing 0, 0.113, 0.225 and 1.2 mg/kg/day ethion for two years. Decreased plasma cholinesterase activity was seen in both males and females in the 1.2 mg/kg dose group; based upon this result, the NOEL for systemic toxicity is 0.225 mg/kg/day; and the LEL is 1.2 mg/kg/day. No evidence of oncogenic effects of ethion was found in treated mice.

4. Teratogenicity (Developmental Effects)

The 1982 Registration Standard for ethion required teratology studies. These data were reviewed by the Agency and determined to be acceptable. Under the conditions of the studies reviewed, no teratogenic effects of ethion were observed. Ethion was administered via gavage to groups of pregnant female rats (25/dose) at doses of 0, 0.2, 0.6, and 2.5 mg/kg from gestation days 6 to 15. Ethion caused an increase in the incidence of hyperactivity in the dams. In the high dose (2.5 mg/kg) group fetuses, an increase in the incidence of delayed ossification of pubes was seen. Based upon these findings, the NOEL for maternal toxicity is 0.6 mg/kg; and the maternal LEL is 2.5 mg/kg. The NOEL for developmental toxicity is 0.6 mg/kg; and the LEL is 2.5 mg/kg.

Groups of artificially inseminated female rabbits (17/dose) received (via gavage) ethion at doses of 0, 0.6, 2.4, and 9.6 mg/kg from gestation days 6 to 18. In the mid and high dose females, an increased incidence of orange-colored urine and reduced body weight gain was seen. Reduced food consumption was also found in high dose females. An increased incidence of fused sternal centra in the fetuses of the high dose group was found. Based upon these findings, the NOEL for maternal toxicity is 0.6 mg/kg and the LEL is 2.4 mg/kg; the NOEL for developmental toxicity is 2.4 mg/kg and the LEL is 9.6 mg/kg.

5. Reproduction and Fertility Effects

Reproductive and fertility effects data were required in the 1982 Registration Standard for ethion. These studies were reviewed by the Agency and determined to be acceptable in supporting the registration of ethion. Ethion has a reproductive NOEL of 1.25 mg/kg/day (HDT) and a systemic NOEL of 1.25 mg/kg/day for males and 0.2 mg/kg/day for females. These findings were based on tests in which ethion was administered to groups of F₀, F₁, and F₂ male and female rats (15 males/dose and 30 females/dose) at dietary concentrations of 0, 0.1, 0.2, and 1.25 mg/kg/day. A decrease in serum cholinesterase activity was observed in the F₁ and F₂ high-dose females (1.25 mg/kg/day).

6. Mutagenicity Testing

The mutagenicity data submitted as a requirement of the 1982 Registration Standard were determined to be insufficient in satisfying the data requirements for mutagenicity testing. One study, an in vivo cytogenic assay in male rats, was not conducted according to the accepted procedures for performing rat bone marrow cytogenetic assays. Additional studies are necessary to fulfill this requirement.

There were no mutagenic effects observed in the studies reviewed for this registration standard.

Gene mutation test

An acceptable Ames assay was reviewed and the data show that ethion at the concentration range of 0.625 to 10.0 nl/ml does not produce mutagenic effects in five strains of Salmonella typhimurium (TA-98, TA-100, TA-1535, TA-1537, and TA-1538).

Structural chromosome aberration test

An in vivo cytogenetic assay in male rats was reviewed. In this study, 5 male rats/dose group received ethion at doses of 0, 4.7, 14, 47, and 140 mg/kg. All the animals in the 140 mg/kg died. The data indicated that ethion at a dose range of 4.7 to 47 mg/kg did not induce chromosome aberrations in male rats. However, this study is unacceptable and another study is required.

Test for other genotoxic effects

An unscheduled DNA synthesis (UDS) in rat primary hepatocyte study was reviewed and no evidence of induction of UDS was found at the ethion dose levels of 100, 500, 2500, 5000, and 10,000 ug/plate. However, this study is not acceptable and another genotoxic effects study is required.

7. Special Studies

Metabolism

The 1982 Registration Standard for ethion required a general metabolism study. Three studies were submitted in response to the Registration Standard. They are currently under review. The registrant will be notified if additional studies are required.

Domestic animal safety

Studies are not required at this time.

Dermal Absorption

Dermal absorption studies are not required at this time.

8. Information on Human Effects

A study with human volunteers for an assessment of the effects of ethion on human plasma and erythrocyte cholinesterase activity was reviewed.

A group of adult male volunteers (9) was randomly divided into a control group (3 males) and a treatment group (6 males). The treatment group received ethion serially and orally (gelatin capsule) at dose levels of 0.05, 0.075, 0.1, and 0.15 mg/kg. Significant reduction of plasma cholinesterase activity was seen at doses of 0.075 mg/kg and above. Based upon the data reviewed, a NOEL of 0.05 mg/kg/day and a LEL of 0.075 mg/kg/day were established.

C. Environmental Characteristics and Effects

1. Ecological Effects

In the 1982 Ethion Registration Standard, the Agency determined that the Avian Dietary LC_{50} , the Acute Fish LC_{50} and the Acute Toxicity to Freshwater Aquatic Invertebrates were acceptable in supporting the registration of ethion. The Agency required the submission of two studies relating to the ecological effects: Acute Avian Oral Toxicity, and Acute Toxicity to Estuarine and Marine Organisms. An updated ecological effects profile is provided below.

Avian Acute Oral and Dietary Toxicity

The avian acute oral and dietary toxicity ranged from practically nontoxic to highly toxic depending on the species of bird. These tests showed that ethion is highly toxic to songbirds (Red-winged blackbird LD_{50} = 45 mg/kg) and moderately toxic to medium size birds such as the bobwhite quail (LD_{50} = 128.8 mg/kg) and starlings (LD_{50} >304 mg/kg). Avian dietary studies showed that ethion is practically nontoxic (LC_{50} >5000 mg/kg) to larger upland gamebirds and waterfowl (ring-necked pheasant and Mallard duck). No additional avian toxicity studies are required.

Avian Chronic Toxicity Testing

Chronic toxicity testing (avian reproduction) is required to support registration when:

1. The pesticide is persistent in the environment to the extent that toxic amounts on avian food could be present.
2. Use of the compound may subject birds to repeated or continuous exposure.
3. The pesticide is stored or accumulated in plant or animal tissue.

Because of ethion's persistence, demonstrated bioaccumulation potential, and acute avian toxicity, an avian reproduction study is required.

Aquatic Organisms - Acute Toxicity

Based on the Agency's review of available aquatic studies, technical ethion is very highly toxic to freshwater and marine fish. Acute toxicity ranges from an LC_{50} of 49 ppb for Atlantic silversides to an LC_{50} of 720 ppb for cutthroat trout and flathead minnows.

Ethion was found to be very highly toxic to freshwater invertebrates (Pteronarcys, Daphnia, Simocephalus, and Gammarus). The acute toxicity ranged from 0.056 to 4.7 ppb. The toxicity of ethion to marine/estuarine invertebrates is also very high, ranging from 5.6 ppb to 15 ppb. No additional testing is required.

Ethion is moderately toxic to oyster embryos. A NOEL was calculated to be 1.1 ppm. No additional testing is required.

Ethion was found to readily accumulate in the tissues of fish. Edible fish tissue sampled after 14 and 42 days of exposure to ethion (0.66 - 2.6 ppb) contained 29% of the tagged ethion residues, and the viscera contained 41 % of the tagged ethion residues.

Honeybee Acute Toxicity

As indicated in the 1982 Registration Standard, ethion was found to be practically non-toxic to honeybees (LD_{50} 20.55 ug/bee). No additional data requirements pertaining to honeybee toxicity will be imposed at this time.

Endangered Species

Because of the demonstrated toxicity of ethion to nontarget fish and aquatic invertebrates, ethion has been identified by the Office of Endangered Species (OES), U.S. Fish and Wildlife Service (FWS) as being likely to negatively impact endangered aquatic organisms when applied to certain crops (i.e., citrus, corn, sorghum and cotton). The Agency is developing a program to reduce or eliminate exposure to these vulnerable organisms, and will issue notice of any product labeling requirements, other than those identified in this registration standard, when the program has been developed and implemented.

Summary of Risk Assessment for Avian and Aquatic Organisms

Ethion is very highly toxic to several species of freshwater and marine fish and aquatic invertebrates. Although chronic testing and an adequate field testing have not been submitted to the Agency for review, the calculated EEC values strongly suggest that certain agricultural uses of ethion (runoff from citrus groves in particular) may result in acutely toxic situations for aquatic organisms. A field dissipation study is required.

Ethion appears to pose little acute hazard to upland gamebirds and waterfowl at current application rates, but may present an acute hazard to small songbirds feeding in the treated area.

2. Environmental Fate

In the 1982 Ethion Registration Standard, the Agency required the following environmental fate testing; hydrolysis, photodegradation in water and soil, aerobic and anaerobic soil metabolism, leaching, field dissipation (terrestrial), and fish bioaccumulation (lab). The data submitted in response to the 1982 standard have been reviewed. The only data requirements that have been satisfied are aerobic soil metabolism and fish bioaccumulation. Additional studies for photodegradation (in water, soil and air), anaerobic soil metabolism, leaching, field dissipation (terrestrial), and fish accumulation are required.

The hydrolysis data requirement has been satisfied for pH 5 and 7. The hydrolysis study for pH 9 has been classified as supplemental because of the possibility that the buffer (borate) may have reacted with the parent or degradates. The registrant has the option of addressing this issue or conducting another study using a different buffer. Additional studies are required to satisfy the remaining environmental fate requirements.

The 1982 Registration Standard data requirements for environmental chemistry did not include laboratory volatility tests. Since the issuance of the 1982 standard, the Agency has instituted specific criteria for requiring laboratory volatility. A laboratory volatility study is required for ethion.

The data requirements for confined accumulation in rotated crops and field accumulation for rotated crops were waived in the 1982 standard. The waiver was granted based on usage estimates at that time. However based on current use estimates of ethion, the data requirements for confined accumulation in rotated crops are now being imposed. The field accumulation data for rotated crops are reserved.

While the data base regarding environmental fate for ethion is incomplete, the Agency has made the following determination based on aerobic soil metabolism. A major degradation pathway for ethion appears to be soil metabolism, with CO₂ forming the principal degradate.

The bioaccumulation of ethion residues in fish cannot be fully assessed until persistence and mobility data are provided from the field dissipation and leaching studies. However, based on acceptable and supplemental data, ethion appears to be resistant to hydrolysis (except at very alkaline pH), photolyses in water and on soil (half-lives of 58 and 51 days, respectively), degrades with a half-life of 69-102 days (in the aerobic soil metabolism study), and its major metabolite is carbon dioxide.

3. Ground water and Leaching Assessment

The 1982 Registration Standard did not address the issue of ground water contamination. The Agency has reviewed supplemental data and determined that ethion is immobile and moderately persistent. Ethion is chemically bound to nearby soil particles and is not expected to leach. No ground water monitoring requirements for ethion are being imposed at this time. However a field dissipation study to determine the depth of leaching is required.

4. Worker Protection

The Agency has determined that ethion presents an acute hazard to exposed persons as evidenced by the acute toxicity classification shown in Table 2 and the plasma red blood cell and brain cholinesterase inhibition in both the 21-day dermal studies in rabbits and the 90-day feeding studies with dogs and rats.

TABLE 2 - Acute Toxicity for Major Routes of Exposure to Ethion

<u>Route of Exposure</u>	<u>Test Results</u>
Acute Oral	LD ₅₀ = 191 mg/kg (males) LD ₅₀ = 21 mg/kg (females)
Acute Dermal	LD ₅₀ = 838 mg/kg
Acute Inhalation	LC ₅₀ = 0.45 mg/kg (females) LC ₅₀ = 2.31 mg/kg (males)

The 1982 Ethion Registration Standard cited a significant history of pesticidal poisoning incidents associated with the use of ethion. Between 1976 and 1985, ethion was one of the top ten pesticides associated with reentry poisonings in California.

Based on the acute hazard to exposed persons the 1982 Registration Standard recommended the following:

For each crop, the registrant must propose an acceptable reentry interval. This proposed interval may be based on any of the following:

- a. The longest (most restrictive) existing reentry interval imposed by the States (currently those in California - 30 days for citrus, 14 days for peaches, nectarines, and grapes, 2 days for other crops).
- b. Data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on the inherent toxicity of the chemical.
- c. Determination of the time beyond which there are no detectable foliar residues (under appropriate climatic conditions) in the areas where the chemical will be applied.

The registrants of products containing ethion had until December 31, 1985 to submit the required data or adopt the most restrictive state imposed reentry intervals. Since none of the reentry data criteria specified in the 1982 Registration Standard have been submitted to the Agency for review, the Agency is requiring that the registrants of ethion products adopt the most restrictive reentry intervals imposed by the States. The following interim reentry intervals will be imposed until appropriate exposure data has been received from the registrants and evaluated by the Agency:

<u>Crop</u>	<u>Reentry interval after last application</u>
Citrus	30 Days
Peaches	14 Days
Nectarines	14 Days
Grapes	14 Days
All other crops	2 Days

D. Tolerance Reassessment

1. Tolerances Issued

Tolerances for residues of ethion in or on raw agricultural commodities and animal products are published in 40 CFR 180.173. Food and feed additive tolerances for ethion have been established for dried tea and raisins and are published in 40 CFR 185.2750 (formerly 21 CFR 193.190). A feed additive tolerance for ethion has been established for dehydrated citrus pulp and is published in 40 CFR 186.2750 (formerly 21 CFR 561.230). All tolerances are expressed in terms of ethion and its oxygen analog (S-[[diethoxyphosphinothioyl]thio]methyl 0,0-diethyl phosphorothioate]. EPA has evaluated the residue and toxicity data supporting these tolerances and the data submitted in response to the 1982 Registration Standard. The following were considered during this evaluation:

- o Whether the tolerances are adequate to protect the public health, including that of sensitive subpopulations.
- o Whether the current tolerances and food/feed additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA sec. 24(c)).
- o Whether group tolerances can be established in accordance with 40 CFR 180.34(f).

- o Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- o Whether the tolerances are expressed accurately and in current terminology.

The regulatory determinations resulting from EPA's review are set out in Section IV.A., Regulatory Positions and Rationales.

TABLE 3 - Summary of Tolerances Issued for Ethion

Commodities	Tolerances (PPM) Maximum Residue Level			
	US	International Canadian	Mexican	Codex
Almonds	0.1	0.1	0.1	0.1 ¹
Almond, hulls	5.0			
Apples	2.0	2	2	2 ¹
Apricots	0.1	none	none	0.1 ¹
Beans	2.0	1	2	none ²
Cattle, fat	2.5	2.5	none	
Cattle, meat	2.5	2.5	none	2.5 ¹
Cattle, mbyp	1.0	2.5	none	1 ¹
Cherries	0.1	none	none	0.1 ¹
Chestnuts	0.1	none	0.1	0.1 ¹
Citrus	2.0	2	2	2 ¹
Citrus, pulp	10			
Corn, fodder	14	none	none	none ²
Corn, forage	14	none	14	none ²
Corn, grain	0.1	none	0.1	0.05 ³
Cottonseed	0.5	none	0.5	0.5 ¹
Cucumbers	0.5	0.1	0.5	0.5 ¹
Eggs	0.2	none	none	0.2 ¹
Eggplants	1.0	0.1	1	1 ¹
Filberts	0.1	none	0.1	0.1 ¹
Goats, fat	0.2	none	none	0.2 ¹
Goats, meat	0.2	none	none	0.2 ¹
Goats, mbyp	0.2	none	none	0.2 ¹
Grapes	2.0	2	2	2 ¹
Raisins	4.0			
Hogs, fat	0.2	none	none	0.2 ¹
Hogs, meat	0.2	none	none	0.2 ¹
Hogs, mbyp	0.2	none	none	0.2 ¹
Horses, fat	0.2	none	none	0.2 ¹
Horses, meat	0.2	none	none	0.2 ¹
Horses, mbyp	0.2	none	none	0.2 ¹
Melons	2.0	0.1	2	2 ¹
Milk, fat	0.5	none	none	0.2 ⁴
Nectarines	1.0	none	none	1.0 ¹
Onions	1.0	0.1	1	1 ¹
Peaches	1.0	1.0	1.0	1.0 ¹
Pears	2.0	2	1	2 ¹
Pecans	0.1	none	0.1	0.1 ¹
Peppers	1.0	0.1	1	1 ¹
Pimentos	1.0	0.1	none	none ²
Plums (fresh prunes)	2.0	1.0		2.0 ¹
Poultry, fat	0.2	none	none	0.2 ¹
Poultry, meat	0.2	none	none	0.2 ¹
Poultry, mbyp	0.2	none	none	0.2 ¹

Summary of Tolerances Issued for Ethion (cont.)

Commodities	Tolerances (PPM)		Maximum Residue Level	
	US	International		
		Canadian	Mexican	Codex
Sheep, fat	0.2	none	none	0.2 ¹
Sheep, meat	0.2	none	none	0.2 ¹
Sheep, mbyb	0.2	none	none	0.2 ¹
Sorghum, forage	2.0	none	2.0	none ²
Sorghum, grain	2.0	none	2.0	none ²
Squash, summer	0.5	0.1	0.5	0.5 ¹
Strawberries	2.0	1.0	2.0	2.0 ¹
Tea (dried)	10.0	none	none	5.0 ⁵
Tomatoes	2.0	0.5	2	2 ¹
Walnuts	0.1	none	0.1	0.1 ¹

1. Established Codex Maximum Residue Level (MRL) is numerically identical to U.S. Tolerance.
2. No Codex MRL has been established, therefore, no questions of compatibility exist with respect to Codex MRL.
3. A Codex MRL of 0.055 ppm exist for residues of ethion per se in or on maize. This level is lower than that of the U.S..
4. U.S. Tolerance is higher.
5. (Green, black tea): An assessment regarding the potential for compatibility between the permanent Codex MRL and the U.S. tolerance will not be made until the adequacy of the U.S. tolerance has been ascertained.

2. Residue Data

An update on the residue chemistry data supporting tolerances for ethion is as follows:

A. Nature of Residue in Plants

No information regarding the uptake or metabolism of ethion by plants was available for review in the 1982 Registration Standard. The 1982 Standard required data depicting the metabolism of [^{14}C]ethion in plants and data from a [^{14}C]ethion study to determine the uptake and distribution of ethion and/or its degradation products. Data were submitted in response to the outstanding requirements. These data were reviewed and the Agency concluded that the metabolism of ethion in citrus fruits was adequately described. The following are required:

- o Data depicting the distribution and metabolism of methylene-labeled [^{14}C] ethion in or on grapes and cottonseed.

B. Nature of Residue in Animals

The nature of residues of ethion in animals is not adequately understood. The data reviewed in the residue chemistry chapter of the 1982 Standard was judged to be insufficient because only the distribution of ^{32}P -residues in the tissues and milk of cattle were depicted and none of the residues were characterized. The 1982 standard required data depicting the rates and routes of elimination of radiolabeled ethion from food animals (including a materials balance), identification of metabolites formed, the sites of metabolism, and the relative levels of ethion and metabolites and their distribution in cattle tissues and milk. Data pertaining to metabolism in ruminants and poultry were submitted in response to these requirements and reviewed. The data were deemed insufficient due to a lack of characterization of residues in tissues, milk, and eggs. The following additional data are required:

- o Metabolism studies utilizing ruminants and poultry.
- o Data depicting the nature of ethion residues in swine are reserved but will be required if the metabolism studies conducted with ruminants and poultry reveal that the metabolism of ethion differs from that in rats.

C. Residue Analytical Methods

The qualitative nature of the residue in plants and animals has not been adequately described. Therefore, the adequacy of the available analytical methods cannot be ascertained. The GLC/FPD Method for organophosphate compounds published in PAM Vol. I (Protocol II) is in PAM Vol. II as Method I. This method is adequate for enforcement of tolerances for the combined residues of ethion and ethion monooxon in or on plant and animal commodities. However additional analytical methods may be required if the required metabolism studies indicate that additional metabolites constitute residues of toxicological concern in or on plants and livestock.

Methods II and III published in PAM Vol. II will be deleted, since these methods are inadequate for tolerance enforcement. The colormetric method (II) does not determine ethion monooxon or ethion dioxon levels and the cholinesterase inhibition method (III) lacks specificity.

D. Storage Stability Data

No data pertaining to storage stability were discussed in the residue chemistry chapter of the 1982 Ethion Registration Standard and no data requirements for this topic were specified. The Agency now requires that storage intervals and sample storage conditions be reported for all residue data submitted in support of tolerances and that the residue data be accompanied by data depicting the stability of all residues of concern in storage. Data regarding the stability of ethion, ethion monooxon, and ethion dioxon in extracts of apples, corn grain, silage and stover, cucumbers, grapes, and oranges were reviewed by the Agency for the second round review of ethion. These data indicate that ethion, ethion monooxon, and ethion dioxon are stable in extracts of these commodities for up to 6 months of storage at -18°C in glass jars. Additional data reviewed indicate that residues of ethion in fortified surface and pulp extract of strawberries are stable for 227 days stored in brown bottles at $5-8^{\circ}\text{C}$. No data are available on the stability of these residues in processed commodities, meat, milk, poultry, or eggs. The following data are required:

- o The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant and animal commodities. This information must be accompanied by storage stability data reflecting these time intervals and conditions.

E. Crop Group Tolerances

The available data are insufficient to determine whether crop group tolerances are appropriate for the crop groupings listed below:

Bulb Vegetables	Legume Vegetables
Fruiting Vegetables	Cucurbit Vegetables
Pome Fruits	Stone Fruits
Small Fruits & Berries	Tree Nut Group
Cereal Grains	
Forage, Fodder, and Straw of Cereal Grains	

Before granting crop group tolerances for ethion, the Agency is requiring additional residue data for representative crop group members.

F. Residue Data

1. The available data support the established tolerances for the combined residues of ethion and its oxygen analog in or on apricots, cherries, and corn (forage). However, these conclusions may change based on the Agency's review of the outstanding plant metabolism and storage stability data.

2. The available data reviewed indicate that the established tolerances for the combined residues of ethion and its oxygen analog in or on citrus fruits, apples, and pears are too low. Tolerance revisions and/or amended use directions (i.e. lower maximum application rates or implementation of preharvest intervals) must be proposed for the crops and appropriate supporting residue data must be submitted to the Agency for evaluation. (For crop specific data requirements, refer to the Data Appendices, Table A - Generic Data Requirements for Ethion, Residue Chemistry 171-4).

3. Additional data are required to assess the established tolerances for the combined residues of ethion and its oxygen analog in or on onions, beans (succulent and dried), tomatoes, peppers, melons, summer squash, peaches, plums (fresh prunes), grapes, strawberries, almonds, almond hulls, pecans, walnuts, corn grain, sorghum grain, corn fodder, sorghum forage, cottonseed, and dried tea. (For crop specific data, refer to the Data Appendices, Table A - Generic Data Requirements for Ethion, Residue Chemistry 171-4).

4. The data requested for crops listed parenthetically may, by translation, be used to assess the tolerances for residues in or on the following commodities: eggplants and pimentos (peppers), cucumbers (summer squash), filberts and chestnuts (walnuts), pears (apples).

It should be noted, however, that translated data, for instance cucumbers for residues on summer squash, may not be used to support a crop group tolerance.

5. The adequacy of the established food additive tolerance for residues in raisins and the need for a feed additive tolerance for residues in dry grape pomace and raisin waste will be determined on receipt of the data requested to assess the established tolerance for residues in or on grapes. The established feed additive tolerance for residues in dried citrus pulp and the need for a food additive tolerance for residues in citrus oil will be determined on receipt of the data requested to assess the established tolerance for residues in or on citrus fruits.

6. Processing studies are needed for corn, sorghum, tomatoes, beans, plums (fresh prunes), and cottonseed.

7. Data must be submitted and a tolerance must be proposed for residues in or on sorghum fodder. If not, then a feeding restriction must be imposed.

8. The adequacy of the tolerances covering residues of ethion in meat, milk, and eggs, cannot be determined until the outstanding data for plant and animal metabolism, storage stability, and magnitude of residue in feed commodities have been evaluated.

3. Exposure Analysis:

Chronic Exposure Analysis

The chronic TAS analysis used a reference dose (PADI) of 0.0005 mg/kg body weight/day, based on a NOEL of 0.05 mg/kg body weight/day and an uncertainty factor of 100 from a 21-day human oral dosing study. The acute TAS analysis used a NOEL of 0.05 mg/kg body weight for cholinesterase inhibition from a human study. This is the same NOEL on which the reference dose for chronic exposure is based.

The TAS chronic exposure analysis uses tolerance level residues and assumes that 100 percent of the crop is treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall population and 22 population subgroups. For an exposure estimate more closely approximating actual exposure, the Anticipated Residue Contribution (ARC), can be calculated using the anticipated residue data. Anticipated residue data used in the chronic exposure assessment for ethion consisted of FDA surveillance monitoring data; processing studies; field residue data for livestock feed items (corn and sorghum), and livestock feeding studies submitted by the registrant. The TMRC and ARC exposure summaries for the overall population, non-nursing infants, and children age 1 to 6 are compared below:

Ethion TMRC-ARC Exposure Summary

	<u>Overall U.S. Population</u>	<u>Non-Nurs. Children Infants</u>	<u>Age 1 -6</u>
TMRC	0.016696 ^a 3339.3 ^b	0.042388 8477.7	0.038054 7610.7
ARC	0.000567 113.3	0.000417 83.4	0.000551 147.8

^a Estimated exposure in mg/kg body weight/day.

^b Exposure expressed as a per cent of the PADI.

The Agency has concluded that no chronic health effect is expected from the use of ethion even though the PADI has been exceeded for the overall U.S. population and children (1-6) because the primary residue contribution is due to tea, based on the established tolerance for the raw, unbrewed commodity. When the required brewing study has been received, it is expected that the anticipated residues from tea will be significantly reduced.

Acute Exposure Analysis

The TAS acute exposure analysis estimates the distribution of single-day exposure for the overall U.S. population and certain population subgroups. The analysis evaluates individual food consumption, as reported by respondents in the 1977-78 USDA Nationwide Food Consumption Survey (NFCS), and accumulates exposure to ethion for each food consumed for which an ethion residue value exists. [Each analysis assumes that ethion residues are present at anticipated residue levels (ARC) in the entire supply of a food commodity and that 100% of the commodities are treated].

The exposure distribution is compared to the NOEL observed in the acute toxicity study. Margins of Safety (MOS) for the average consumer are calculated according to the following relationship (shown for the overall U.S. population):

$$\begin{aligned}\text{Average MOS} &= \text{NOEL/Exposure (ARC)} \\ &= 0.05 \text{ mg/kg} / 0.008219 \text{ mg/kg} \\ &= 6\end{aligned}$$

The following considerations were used in conducting the TAS acute exposure analysis:

1. The entire supply of commodities that may be treated with ethion do in fact contain ethion residues at the maximum levels observed in field studies or at tolerance levels. Tolerance levels were used for strawberries, pears (fresh and dried), tea, watermelon, tomatoes, and beans because available field study data are inadequate. Also proposed tolerances were used for apples and pears since available data indicate that the established tolerance is too low.
2. All foods on which ethion residues may exist that were consumed by a participant in the NFCS are assumed to be eaten at one meal. (Usually exposure would likely occur over an extended period throughout the day but TAS assumes that the entire exposure occurs at one sitting and therefore is conservative).
3. Exposure analyses were conducted for the general U.S. population, infants, children aged 1-6, adult females and adult males. It is estimated that 94% of infants will consume at least one food on which ethion is registered; it is estimated that essentially every member of the overall population, children aged 1 to 6, and adult females and males consume at least one commodity which may have ethion residues. These estimates are also based on the NFCS Survey.

Based on exposure distributions calculated from all commodities on which ethion may be used, 45 percent of the general population is expected to have a MOS of less than 10 for cholinesterase inhibition. The percentage of consumers in subgroup population expected to have a MOS of less than 10 is: infants (61%); children aged 1 to 6 (63%); adult females (40%); adult males (41%).

In addition to the analyses described above, separate TAS acute exposure analyses were conducted for specific food commodities and commodity groups. The results of the analyses are presented in Table 4 under the categories listed.

- o Percentage of the population expected to consume at least one food which may contain ethion residues (% Consumers).
- o The average Margin of Safety (Avg. MOS) for those members of the population expected to consume at least one food which may contain ethion residues based on average consumption (exposure) of the specific food.
- o The percentage of the population expected to have an MOS of less than 10 (% Cons. <10).
- o The minimum Margin of Safety (Min. MOS) is lowest Margin of Safety expected for some member of the population subgroup. The low MOS would be expected for those individuals having the highest exposure, presumably those who eat the most.

The results of this commodity specific TAS analysis show that:

1. There are seven commodity groups for which no member of any of the TAS population groups is expected to have a MOS less than 10 because of ethion residues: grapefruits, apricots, cherries, and nectarines, eggs, grains, meats, nuts and poultry.
2. There are eight commodity groups for which the minimum MOS for all five TAS population groups is less than 10: apples, and pears; grapes; melons; tomatoes; dry beans; succulent beans; strawberries and citrus fruits other than oranges and grapefruit; and plums and prunes.
3. There are four commodity groups for which the average MOS is generally greater than 10 but one or more population groups have a segment of the population estimated to have a MOS for cholinesterase inhibition less than 10: peaches; miscellaneous vegetables (such as onions, peppers, and squash); tea; and oranges.

TABLE 4: ETHION ACUTE EXPOSURE ANALYSIS SUMMARY

	% Consumers	Avg. MOS	%Cons. < 10	Min MOS
TOTAL				
U.S. Population	100	6	45	< 1
Infants	94	2	61	< 1
Children Aged 1-6	100	3	63	< 1
Adult Females	100	8	40	< 1
Adult Males	100	8	41	< 1
APPLES and PEARS				
U.S. Population	33	7	43	< 1
Infants	49	1	81	< 1
Children Aged 1-6	43	4	47	< 1
Adult Females	30	10	41	1
Adult Males	32	11	38	1
GRAPES				
U.S. Population	27	16	16	1
Infants	5	4	30	< 1
Children Aged 1-6	35	8	20	< 1
Adult Females	24	18	18	1
Adult Males	27	22	14	1
MELONS				
U.S. Population	3	6	53	< 1
Infants	4	7	62	2
Children Aged 1-6	2	3	83	< 1
Adult Females	3	7	51	< 1
Adult Males	3	7	45	< 1
TOMATOES				
U.S. Population	55	18	16	2
Infants	29	14	15	1
Children Aged 1-6	51	9	38	1
Adult Females	55	22	12	3
Adult Males	57	22	12	3
DRY BEANS				
U.S. Population	12	12	8	3
Infants	3	9	34	2
Children Aged 1-6	14	12	29	2
Adult Females	11	28	3	6
Adult Males	13	27	4	6

TABLE 4: ETHION ACUTE EXPOSURE ANALYSIS SUMMARY (cont'd)

	% Consumers	Avg. MOS	%Cons. < 10	Min MOS
SUCCULENT BEANS				
U.S. Population	16	15	17	2
Nursing Infants	10	3	84	< 1
Children Aged 1-6	14	8	51	1
Adult Females	15	17	12	3
Adult Males	16	18	10	3
STRAWBERRIES and OTHER CITRUS				
U.S. Population	31	200	1	6
Infants	3	35	6	1
Children Aged 1-6	28	111	2	3
Adult Females	32	219	1	7
Adult Males	32	236	1	7
PLUMS/PRUNES				
U.S. Population	2	29	5	3
Infants	5	7	50	1
Children Aged 1-6	1	13	27	3
Adult Females	2	37	1	8
Adult Males	2	39	1	8
PEACHES				
U.S. Population	20	85	2	6
Infants	17	9	52	2
Children Aged 1-6	24	48	6	3
Adult Females	18	112	0	13
Adult Males	19	114	0	13
MISCELLANEOUS VEGETABLES				
U.S. Population	61	150	1	8
Infants	28	166	1	7
Children Aged 1-6	59	98	1	3
Adult Females	59	157	1	8
Adult Males	63	175	0	10
TEA				
U.S. Population	27	43	1	8
Infants	2	13	24	2
Children Aged 1-6	14	21	6	5
Adult Females	34	45	0	10
Adult Males	27	50	0	10

TABLE 4: ETHION ACUTE EXPOSURE ANALYSIS SUMMARY (cont'd)

	% Consumers	Avg. MOS	%Cons. < 10	Min MOS
ORANGES				
U.S. Population	30	143	0	17
Infants	18	47	1	7
Children Aged 1-6	34	58	0	13
Adult Females	29	195	0	25
Adult Males	28	218	0	25
GRAPEFRUIT				
U.S. Population	5	198	0	25
Infants	< 1	33	0	13
Children Aged 1-6	1	63	0	17
Adult Females	6	205	0	25
Adult Males	5	244	0	50
APRICOTS, CHERRIES, NECTARINES				
U.S. Population	20	725	0	25
Infants	13	151	0	17
Children Aged 1-6	27	472	0	13
Adult Females	17	758	0	25
Adult Males	19	1042	0	25
EGGS				
U.S. Population	90	12500	0	50
Infants	34	5556	0	50
Children Aged 1-6	92	6250	0	50
Adult Females	90	16667	0	50
Adult Males	92	16667	0	50
GRAINS				
U.S. Population	98	1250	0	50
Infants	59	472	0	50
Children Aged 1-6	99	526	0	50
Adult Females	98	1852	0	50
Adult Males	99	1613	0	50
MEATS				
U.S. Population	98	555	0	50
Infants	49	521	0	50
Children Aged 1-6	99	296	0	50
Adult Females	98	746	0	50
Adult Males	99	581	0	50

TABLE 4: ETHION ACUTE EXPOSURE ANALYSIS SUMMARY (cont'd)

	% Consumers	Avg. MOS	%Cons. < 10	Min MOS
NUTS				
U.S. Population	12	4545	0	50
Infants	2	2632	0	50
Children Aged 1-6	16	2941	0	50
Adult Females	10	5000	0	50
Adult Males	12	5000	0	50
POULTRY				
U.S. Population	25	4167	0	50
Infants	24	2000	0	50
Children Aged 1-6	28	2273	0	50
Adult Females	25	5000	0	50
Adult Males	24	5000	0	50

Summary of Exposure Analysis

In summary, the Agency has concluded that the use of ethion will not result in chronic health effects, since the anticipated residue analysis for chronic exposure does not significantly exceed the PADI for ethion.

There does not appear to be a health risk from short term exposure to ethion residue on grapefruit, stone fruits other than peaches and plums, eggs, grains, meat nuts, and poultry. However, based on the limited data/information available, short term exposure to ethion from residues on peaches, vegetables, tea, and oranges may result in acute cholinesterase inhibition for selected populations, infants and children. Also, short term exposure to ethion residues on apples and pears, grapes, melons, tomatoes dry beans, succulent beans, strawberries (pooled with citrus other than oranges and grapefruit), and plums or prunes may result in acute cholinesterase inhibition in all population groups. Therefore, to permit more accurate, realistic estimates of acute exposure, anticipated residue data are being called in under 40 CFR 158.240 (Reduction of Residue).

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales

Based on the review and evaluation of all available data and other relevant information on ethion, the Agency has made the following determinations. Where label revisions are imposed, specific language has been set forth in the Labeling Section of this Registration Standard.

1. The Agency is considering further regulatory action based on the Agency's dietary exposure concerns.

RATIONALE: The Agency has determined that certain current tolerances may not provide an adequate margin of safety in humans. Short term exposure to ethion residues on apples and pears, grapes, melons, tomatoes, dry beans, succulent beans, strawberries (pooled with citrus other than oranges and grapefruit), and plums and prunes may result in acute cholinesterase inhibition for all TAS population groups. The Agency also has determined that short term exposure to ethion residues on peaches, vegetables, tea, and oranges may result in acute cholinesterase inhibition in selected TAS populations, infants and children.

2. The Agency is not imposing the Restricted Use Classification on all pesticide products containing ethion.

RATIONALE: At present three ethion products are classified Restricted Use because of their high dermal and inhalation toxicity. Two of these products contain 81.9% active ingredient and the other contains 81% active ingredient. The Agency will make a decision regarding the Restricted Use Classification on a product-by-product basis for the remaining products after evaluating the product specific toxicity data submitted in response to Table C.

3. The Agency is not requiring the addition of a ground water advisory statement.

RATIONALE: While certain Environmental Fate Data are incomplete, a review of the available data indicate that ethion is moderately persistent, immobile in soil and is not expected to leach. After a review of the terrestrial field dissipation study, the Agency will determine what regulatory action, if any, is appropriate to protect ground water.

4. Because of the high acute toxicity and documented incidents of farmworker pesticidal poisonings, the following reentry intervals are being imposed on products containing ethion with agricultural use patterns.

Citrus.....30 Days

Peaches

Nectarines

Grapes 14 Days

All other crops ...2 Days

RATIONALE: The 1982 Registration Standard for ethion imposed a 24-hour reentry interval for all crops treated with ethion because of inadequate information on the possible hazards to agricultural workers in orchards and fields. The 24-hour reentry interval was intended as an interim measure and was imposed until adequate reentry data could be generated and evaluated by the Agency. To this end, the 1982 Registration Standard gave the registrants of ethion the option of either developing reentry data or adopting the most restrictive reentry intervals imposed by the States. Since no reentry data have been submitted to the Agency for review, EPA is requiring the registrant of ethion to adopt the most restrictive state imposed reentry intervals.

5. No significant new food uses or increases of tolerances for food or feed items treated with ethion will be considered until the outstanding residue chemistry studies have been submitted and reviewed by the Agency.

RATIONALE: Available animal and plant metabolism and magnitude of residues in plants and livestock data, are insufficient and/or lacking. These data deficiencies preclude the Agency from conducting a full tolerance reassessment.

6. While the required data are under development all currently registered products containing ethion as an active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in the Standard. Registrants must agree to develop and provide additional data, as specified in the Data Appendices, in order to maintain existing registrations.

RATIONALE: Under FIFRA, the Agency may choose not to cancel or withhold registration if the data are missing or inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). The issuance of this Standard provides the mechanism for obtaining necessary data. The data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

7. The Agency has identified certain data that will receive immediate review when submitted.

RATIONALE: Certain of the data being required by the Agency are essential to resolve risk concerns, or may generate the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

<u>Data Requirement</u>	<u>Guideline No.</u>	<u>Description</u>
158.390	132-1, 132-1(2) 133-3&4	Reentry Protection
158.75	231, 323, 333	Applicator Exposure Monitoring
158.77	133-3&4, 232, 234, 132-1	Non-occupational post-application monitoring
158.390	81-1 thru 6	Acute toxicology (Product Specific)
158.240	171-2 thru 5 (including all residue reduction data)	Residue Chemistry

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain ethion, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this registration standard.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The EPA Compendium of Acceptable Uses (for availability, see page 1) lists all registered uses, as well as approved maximum application rates and frequencies.

Terrestrial Food Crop Use:

Alfalfa (seed crop), almonds, apples, apricots, beans, blueberries, cherries, chestnuts, corn (field), cotton, cucumbers, eggplants, filberts, garlic, grapefruit, grapes, leeks, lemons, limes, melons, nectarines, onions (dry & green), oranges, peaches, peanuts, pears, pecans, peppers, pimentos, plums, prunes, sorghum (grain & forage), sorghum (seedcrop), squash (summer), strawberries, tangelos, tangerines, tomatoes, and walnuts.

Terrestrial Non-food Crops:

Bermudagrass, Junipers, ornamental evergreens, pine trees, lawns, ornamental turf, and ornamental plants.

Greenhouse Non-food Crop:

Ornamental plants.

Domestic Outdoor Uses:

Domestic dwellings.

D. LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing this pesticide may be released for shipment by the registrant after September 30, 1990, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing this pesticide may be distributed or sold after September 30, 1991, unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENT

0,0,0',0' - Tetraethyl S,S'-methylene
bisphosphorodithioate%

INERT INGREDIENTS.....%

2. Organophosphate Statement

The label must state that this product contains an organophosphate. This must be identified as part of the product name, or as part of the product identification, or as a separate statement. It may not appear only within the ingredients statement.

3. Use Pattern Statements

a. Manufacturing-Use Products

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Compendium of Acceptable Uses. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

b. End Use Products

All end use product labeling with agricultural uses must be revised to explicitly specify preharvest intervals, the maximum number of applications to the crop per season, and the maximum interval between treatments. If these statements must be supported by data, then the time frame specified in the Table A is applicable, otherwise these labeling revisions must be submitted to the Agency within one year of the date of receipt of this document.

4. Precautionary Statements:

Environmental Hazard Statements

a. Statements for Manufacturing-Use Product

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

b. Statements for End-Use Products

"This pesticide is toxic to fish, and aquatic invertebrates. Fish and aquatic invertebrates may be killed in areas where this pesticide is used. Do not contaminate water when disposing of equipment washwaters."

2. Worker Protection Statements

a. Statements for End Use Products

The protective clothing labeling statements listed below are required on all products containing ethion with the signal words DANGER or WARNING that are applied to agricultural sites, structural pest control sites, or greenhouses.

"Do not rub eyes or mouth with hands. If you feel sick in any way STOP work and get help right away. See Practical Treatment Section of this label."

"Do not apply this product in a way that will contact unprotected workers, either directly or through drift. Only protected handlers may be in the area during application."

"USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING, AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE, AND EARLY REENTRY INTO TREATED AREAS: Protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical resistant gloves; chemical resistant shoes (or chemical resistant shoe covers or chemical resistant boots); and a NIOSH or MSA approved respirator. In addition, mixer/loaders must wear a chemical resistant apron and face shield or goggles.

During equipment repair and cleaning, the respirator need not be worn. During early reentry after sprays have dried or dusts have settled and vapors have dispersed, the respirator need not be worn.

IF MIXING/LOADING IS PERFORMED USING A CLOSED SYSTEM, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: long-sleeved shirt and longlegged pants; shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn when exiting. This clothing is inadequate protection during equipment repair or cleaning, reentry, or pesticide disposal work.

IMPORTANT! If pesticide comes in contact with skin, immediately wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or when using toilet.

AFTER WORK: Wash gloves with soap and water before removing them. Take off all work cloths and shoes. After removing clothing shower using soap and water, then put on clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from household items. Store protective clothing separate from personal clothing. Clean or launder protective clothing after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirator. Protective clothing and equipment that becomes heavily contaminated or drenched must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS MUST BE IN A TOTALLY ENCLOSED VEHICLE."

Reentry Intervals

All products with directions for use on agricultural cultural crops must bear the following reentry intervals and statements listed below:

Citrus.....30 Days

Peaches

Nectarines

Grapes 14 Days

All other crops ...2 Days

"Do not enter or allow entry into treated areas until (sprays have dried/dusts have settled/vapors have dispersed, as applicable) to perform hand labor tasks. A person may enter the area to perform other tasks only if the person is wearing the personal protective clothing listed on the label."

"After (sprays have dried/dusts have settled/vapors dispersed, as applicable) do not enter or allow entry into the treated area until the reentry interval has expired, unless the person entering the treated area is wearing the personal protective equipment listed on the label for early reentry."

Restricted Use:

Three ethion products, two containing 81.9% active ingredient and one containing 81% active ingredient, have been classified Restricted Use based on their dermal and inhalation toxicity. These products must bear the following restricted classification in their product labeling:

"RESTRICTED USE CLASSIFICATION
Due to acute dermal and inhalation
toxicity.

For retail sale to use only by Certified
Applicators or persons under their direct
supervision and only for those uses covered
by the Certified Applicator's Certification."

For all other products containing ethion, the Agency will make a determination concerning the Restricted Uses classification after review and evaluation of the Product Specific Acute Toxicity Data listed in Table C.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B²
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

²Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B³
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

³Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products.

2. If eligible for the generic data exemption⁴, the data requirements listed in Table C.
3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.
4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.
2. If eligible for the generic data exemption, the data requirements listed in Table C.
3. The labeling requirements specified for end use products in Section IV.

⁴If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.⁵

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

⁵Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.
2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of

your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

- a. A list of the members of the consortium;
- b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
- c. Identity of the Registration Standard containing the data requirement;
- d. A list of the products affected (from all members of the consortium); and
- e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

a. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

b. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer

must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Document Processing Desk (RS-0090)
Office of Pesticide Programs - H7504C
U. S. Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

- a. Application for Pesticide Registration (EPA Form 8570-1).
- b. Five copies of draft labeling, including the container label and any associated supplemental labeling.
- c. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table B, you must submit all product specific data.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months of receipt of this document, you must submit:

- a. Application for Pesticide Registration (EPA Form 8570-1).
- b. Five copies of draft labeling, including the container label and any associated supplemental labeling.
- c. Product Specific Data Report (EPA Form 8580-4).

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the time frames set forth in Table B, you must submit all product specific data.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

- a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).
- b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

- a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.
- b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

- a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).
- b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

- a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.
- b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

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GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
 PAI = Pure active ingredient
 PAIRA = Pure Active ingredient, radio labeled
 TEP = Typical end use formulation
 MP = Manufacturing use product
 EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
 B = Terrestrial, non-food
 C = Aquatic, food
 D = Aquatic, non-food
 E = Greenhouse, food

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F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

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6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.
7. Timeframe for submission (Column 7). If column 6 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).
8. Footnotes (at the end of each table). Self-explanatory.

DATA TABLES

TABLE A. GENERIC DATA REQUIREMENTS FOR THE ETHION TECHNICAL GRADE OF THE ACTIVE INGREDIENT.

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials and Production Process	TGAI	Partially	00132773	Yes ¹	12 months
61-3. Formation of Impurities	TGAI	Partially	00132773	Yes ²	12 months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	Partially	00132773	Yes ³	12 months
Physical and Chemical Characteristics					
63-2. Color	TGAI	Yes	00132773	No	
63-3. Physical State	TGAI	Yes	00132773	No ⁴	12 months
63-4. Odor	TGAI	Partially	00132773	Yes	
63-5. Melting Point	TGAI	N/A	00132773	No ⁴	12 months
63-6. Boiling Point	TGAI	Partially	00132773	Yes ⁴	12 months
63-7. Density, Bulk Density or Specific Gravity	TGAI	Partially	00132773	Yes	
63-8. Solubility	TGAI or PAI	Partially	00132773	Yes ⁴	12 months
63-9. Vapor Pressure	TGAI or PAI	Partially	00132773	Yes ⁴	12 months
63-10. Dissociation Constant	TGAI or PAI	N/A	00132773	No ⁴	12 months
63-11. Octanol/Water Partition Coefficient	PAI	Partially	00132773	Yes	
63-12. pH	TGAI	Partially	00132773	Yes ⁴	12 months
63-13. Stability	TGAI	Partially	00132773	Yes ⁴	12 months
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

1. For the Aceto 95% T (EPA Reg. No. 2749-293) the following information must be provided: a description of the procedures used to assure consistent composition of the substance produced (quality control methods),

TABLE A. (Continued).

the name and address of the producer of each beginning material and information concerning the composition of each, the nature of the process (batch or continuous), the proportions of beginning materials and the order in which they are added, the duration of each step of the process and a flow chart of the chemical equations. For the Cheminova 94% T (EPA Reg. No. 4787-10), the name and address of the producer of each beginning material must be provided.

2. For the Aceto 95% T (EPA Reg. No. 2749-293) a discussion regarding the origin of the following potential impurities must be provided: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. For the FMC 88% T (EPA Reg. No. 279-2280) and the Cheminova 94% T (EPA Reg. No. 4787-10) discussion of the possible degradation of ingredients in the product after production, and post-production reactions between the ingredients in these products is required.

3. For the analytical method used for sample analysis of the FMC 88% T (MRID 00132773), statements of accuracy must be submitted. Also, the FMC and Cheminova products must be analyzed (using validated methods) for all impurities discussed under 61-3 (MRID Nos. 00132773 and 00157088) that are of toxicological concern or may be present at > 0.1% (w/w). For the Aceto 95% T (EPA Reg. No. 2749-293) five or more representative batch samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided.

4. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted for the physical and chemical characteristics of the technical grade of the active ingredient. All of these data except for color, physical state, melting point and dissociation constant are required for the Aceto 95% T (EPA Reg. No. 2749-293). In addition, data are required on the following specific physical/chemical characteristics for the products indicated by EPA Reg. Nos. in parentheses: descriptive definition of odor (4787-10);

TABLE A. (Continued).

solubility as determined in g/100 ml of solvent (279-2280 and 4784-10); vapor pressure and octanol/water partition coefficient determined using the purified active ingredient (279-2280 and 4784-10); pH (279-2280) and temperature used to determine pH (4787-10); and stability (279-2280 and 4787-10).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission ¹
158.240 Residue Chemistry					
171-2. Chemical Identity ²					
171-3. Directions for use	EP	(See Index)		Yes ³	24 Months
171-4. Nature of the residue (Metabolism) - Plants	PAIRA and plant metabolites	Partially	00155869 00155870	Yes ⁴	24 Months
171-4. Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00073144 00155875	Yes ⁵	24 Months
171-4. Residue analytical methods	TGAI and metabolites	Yes	00034468 00073094 00073100	Reserved ⁶	24 Months
171-4. Storage stability	TEP, or TGAI and metabolites	Partially	00073152 00155504	Yes ⁷	24 Months

(continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
171-4. Magnitude of residue in Plants					
Bulb Vegetables	TEP	Partially	00073085	Yes ⁸	24 Months
- Onions			00073152		
Legume Vegetables	TEP	Partially	00073085	Yes ⁹	24 Months
- Beans				Yes ¹⁰	24 Months
Fruiting Vegetables	TEP	Partially	00073095	Yes ¹¹	24 Months
- Eggplant					
- Peppers	TEP	Partially	00073189	Yes ¹²	24 Months
- Pimientos	TEP	No	N/A	Yes ¹³	24 Months
- Tomatoes	TEP	Partially	00073133	Yes ¹⁴	24 Months
				Yes ¹⁵	24 Months
Cucurbit Vegetables	TEP	Partially	00073806	Yes ¹⁶	24 Months
- Cucumbers	TEP	Partially	00073152	Yes ¹⁷	24 Months
- Melons	TEP	Partially	00153160	Yes ¹⁸	24 Months
- Squash					
Citrus Fruits Group	TEP	Partially	00073143	Yes ¹⁹	24 Months
			00155580		

(continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Pome Fruits					
- Apples	TEP	Partially	00073808	Yes ²⁰	24 Months
- Pears	TEP	Partially	00073083	Yes ²¹	24 Months
			00109285	00155850	
Stone Fruits					
- Apricots	TEP	Yes	00073162	Reserved ²²	24 Months
- Cherries	TEP	Yes	00073162	Reserved ²⁴	24 Months
- Nectarines	TEP	Partially	00073195	Yes ²³	24 Months
- Peaches	TEP	Partially	00073082	Yes ²⁴	24 Months
- Plums (fresh prunes)	TEP	Partially	00073083	Yes ²⁵	24 Months
			00109285	Yes ²⁶	24 Months
Small Fruits and Berries					
- Grapes	TEP	Partially	00073083	Yes ²⁷	24 Months
			00109285	00155850	
- Strawberries	TEP	Partially	00034874	Yes ²⁸	24 Months
Tree Nuts					
- Almonds	TEP	Partially	00073095	Yes ²⁹	24 Months
- Chestnuts	TEP	No.	N/A.	Yes ³⁰	24 Months
- Filberts	TEP	Partially	00073162	Yes ³¹	24 Months
- Pecans	TEP	No	N/A.	Yes ³²	24 Months
- Walnuts	TEP	Partially	00073162	Yes ³³	24 Months
Cereal Grains					

(continued).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
- Corn	TEP	Partially	00073132 00073175 00159983	³⁴ Yes ³⁵ Yes	24 Months 24 Months
- Sorghum	TEP	Partially	00034311	³⁶ Yes ³⁷ Yes	24 Months 24 Months
Forage, Fodder, and Straw of Cereal Grains Group					
- Corn forage and fodder	TEP	Partially	00073173	³⁸ Yes	24 Months
- Sorghum forage and fodder	TEP	Partially	00034311	³⁹ Yes	24 Months
Miscellaneous					
- Cottonseed	TEP	Partially	00073158 00073160	⁴⁰ Yes ⁴¹ Yes	24 Months 24 Months
- Tea	TEP	Partially	00073053	⁴² Yes	24 Months
171-4. Magnitude of residue in- TGAI or Meat/Milk/Poultry/Eggs plant metabolites		Partially	00073153 00073138 00073161 00155850	Reserved ⁴³	24 Months
171-5. Reduction of Residue	TEP	No		⁴⁴ Yes	24 Months

1. Data must be submitted within the indicated time frame, based on the date of this Guidance Document.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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2. The same chemical identity data are required as under 158.150-190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.
3. The registrant must amend all pertinent labels to specify a maximum single application rate and a maximum seasonal application rate or a limit on the number of applications permitted per season; rates must be expressed in terms of amount of active ingredient per unit area. In addition, the minimum time interval between repeat applications must be specified. All requested residue data must reflect the maximum number of applications and minimum interval between treatments specified on the labels or proposed by the registrant to appear on the labels.
4. Data depicting the distribution and metabolism of methylene-labeled [^{14}C]ethion in or on grapes and cottonseed. A completely characterized test substance representative of technical ethion (including impurities) used in commercial formulations must be applied foliarly at rates sufficiently high to permit characterization of ^{14}C -residues. The identities of residues in or on mature plant parts must be determined and confirmed in order to elucidate terminal residues. Quantitative data must also be provided. Representative samples must be analyzed using GLC/FPD Method I in PAM Vol. II to ascertain that all residues of concern are determined. The Registrant is urged to complete and submit all plant metabolism studies to the Agency for review prior to initiating residue field trials and processing studies.
5. Metabolism studies utilizing ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with [^{14}C]ethion at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined and confirmed in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using the GLC/FPD Method I in PAM, Vol. II to ascertain that the methods are capable of adequately recovering and identifying all residues of toxicological concern. Data depicting the nature of ethion residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of ethion in these animals differs from that in rats.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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6. Additional analytical methods may be required if the metabolism studies requested indicate that additional metabolites constitute residues of toxicological concern in or on plants or livestock.

7. The sample storage conditions and intervals must be supplied for all required and previously submitted residue data for plant and animal commodities. Storage stability data in support of previously submitted residue data are required for only those samples deemed to be useful for tolerance assessment. Data are also required which depict the decline in levels of ethion residues of concern in commodities stored under the range of conditions and for the range in intervals specified. Crop samples bearing measurable weathered residues or fortified with ethion residues of concern and fortified meat, milk and egg samples must be analyzed immediately after harvest or fortification and again after storage intervals that represent actual residue sample storage conditions and allow for reasonable delays in sample analysis. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites must be used. However, if field weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the Registrant is referred to an August, 1987 Position Document on the Effects of Storage on Validity of Pesticide Residue Data available from NITS under order no. PB 88112362/AS.

8. Data depicting the ethion residues of concern in or on green and dry bulb onions harvested following multiple broadcast soil-incorporated applications of the 10% G formulation at 4 lb ai/A. Tests must be conducted in ID and OR.

9. Data depicting ethion residues of concern in or on beans (succulent and dried) harvested 2 days following the last of multiple foliar applications of the 4% D formulation at 0.8 lb ai/A, a representative EC formulation at 0.5 lb ai/A and the 25% WP at 0.5 lb ai/A. Data depicting ethion residues of concern in or on beans harvested 4 days following the last of multiple foliar applications of the 4% D at 1.6 lb ai/A and the 25% WP and an EC formulation at 1 lb ai/A. Only ground application data are needed for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. Tests must be conducted in CA(12% dry), MI(21% dry, 7% succulent), NE(13% dry) or CO(10% dry), NY(10% succulent), ND(19% dry), OR(23% succulent), and WI(41% succulent) which accounted for ca. 80% of the 1987 dry bean production (Ag.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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Statistics Board, NASS, USDA, 1988, Annual Crop Statistics, p. 48) and 80% of the 1986 snap bean production (Ag. Statistics Board, NASS, USDA, 1987, Vegetables, 1986 Summary, p. 45).

10. Data depicting the potential for concentration of ethion residues of concern in or on the canary residue from beans bearing measurable, weathered residues. If the data indicate the potential for concentration of residues, the registrant must propose an appropriate feed additive tolerance.

11. The data requested for peppers will be translated to eggplants.

12. Data depicting the ethion residues of concern in or on peppers harvested on the day of the last of multiple foliar applications of the 25% WP, the 4% D, and a representative EC formulation at 0.5 lb ai/A. Only ground application data are needed for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. Tests must be conducted in CA(18% sweet, 27% hot), FL(23% sweet, 2% hot), and TX(16% sweet, 10% hot). These states accounted for ca. 57% of the 1982 sweet pepper production and ca. 79% of the 1982 hot pepper production if TX is representative of NM(40%) (1982 Census of Agriculture, Vol. 1, Part 51, p. 349).

13. The data requested for peppers will be translated to pimentos.

14. Data depicting the ethion residues of concern in or on tomatoes harvested 2 days following the last of multiple foliar applications of the 25% WP and a representative EC formulation at 0.5 lb ai/A and the 4% D formulation at 0.8 lb ai/A. Only ground application data are needed for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. Tests must be conducted in CA which accounted for ca. 26% of the tomatoes grown for fresh market and 85% of the tomatoes grown for processing in 1985. Also, tests must be conducted in FL where 47% of the fresh market tomatoes were grown and in OH, IN, or MI, which together produced ca. 10% of the tomatoes grown for processing (preliminary 1985 data, Agricultural Statistics, 1986, p. 172, USDA).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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15. A processing study depicting the combined residues of ethion and ethion monooxon in products (dry pomace, puree, catsup, and juice) processed from tomatoes bearing measurable weathered residues. If residues concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

16. Registrants must either impose a 3-day PHI on all labels that permit use on cucumbers, remove cucumbers from all ethion labels, or submit data to reflect the current 0-day PHI as required under the "Summer Squash" section. If data are submitted for summer squash, they may be translated to fulfill the requirements for cucumbers.

17. Data depicting ethion residues of concern in or on melons (cantaloupes or muskmelons) harvested the day of the last of multiple foliar applications of the 25% WP formulation at 1 lb ai/A applied with ground equipment, and a representative EC formulation at 1 lb ai/A and the 4% D at 1.6 lb ai/A applied with ground equipment, and aerial equipment, in separate tests. Tests must be conducted in CA(58%) and TX(21%), since these states accounted for ca. 80% of the 1982 cantaloupe acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 229).

18. Data depicting ethion residues of concern in or on squash harvested on the day of the last of multiple foliar applications of the 25% WP formulation at 0.5 lb ai/A applied with ground equipment, and a representative EC formulation at 0.5 lb ai/A applied with ground and aerial equipment. Tests must be conducted in CA(15%), FL(21%), GA(7%), NC(4%), MA(4%) or NY(4%), MI(4%), and NJ(6%) which collectively accounted for ca. 70% of the 1982 squash acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 353). Alternatively, all registrants may impose the 3-day PHI specified on FMC labels.

19. The registrant must propose a revised tolerance for ethion residues of concern in or on citrus fruits and submit appropriate supporting residue data for the representative commodities grapefruit, oranges, and

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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lemons. The data must reflect six applications of the 25% WP and a representative EC formulation made at 90-day intervals to oranges and grapefruits and a single application to lemons at 7.5 lb ai/A. Oranges and grapefruits must be harvested on the day of the final treatment and at regular intervals thereafter, and lemons must be harvested 21 days posttreatment. Alternatively, the registrant may propose amendments in the registered uses and a revised tolerance if necessary, and submit appropriate supporting residue data. Tests on grapefruit must be conducted in FL(100%), tests on lemons in CA(75%), tests with oranges in CA(32%) and FL(66%), since these states reflect 1987 U.S. production of ca. 100%, 75%, and 98%, respectively, for grapefruit, lemons, and oranges (Agricultural Statistics Board, NASS, USDA, Crops Database, Jan. 1988). It should be noted that any proposed increase in the tolerance must also be evaluated in terms of toxicological considerations. A decision as to the adequacy of the established feed additive tolerance for residues in dried citrus pulp and the appropriate level for a food additive tolerance for residues in citrus oil will not be made until an adequate tolerance for residues in or on citrus fruits has been established.

20. The registrant must propose a revised tolerance for ethion residues of concern in or on apples and submit residue data depicting ethion residues of concern in or on apples harvested: (i) 20 days following two applications of the 4% D and 4 or 8 lb/gal EC formulations at 2.5 lb ai/A; (ii) 40 days following two applications of the 4% D at 3.6 lb ai/A, and the 25% WP and 4 or 8 lb/gal EC formulations at 5 lb ai/A; and (iii) 60 days following four applications of the 4% D at 3.6 lb ai/A, and the 25% WP and 4 or 8 lb/gal EC formulations at 5 lb ai/A. Applications must be made at 10-day intervals during the fruiting season. Only ground application data are needed for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. Alternatively, the registrant may propose amendments in the registered uses and a revised tolerance if necessary and submit appropriate supporting residue data. Tests must be conducted in CA(7%), MI(11%), NY(10%), and WA(42%) which collectively accounted for ca. 70% of 1987 U.S. apple production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88). It should be noted that any proposed increase in tolerance level must also be evaluated in terms of toxicological considerations.

21. The data requested for apples will be translated to pears.

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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22. On receipt of the required plant metabolism and storage stability data, the need for additional data will be determined.

23. The data requested for peaches will be translated to nectarines.

24. Data depicting ethion residues of concern in or on peaches harvested 30 days following the last of two foliar applications made during the fruiting period using: (i) the 4% D at 2.4 lb ai/A and an EC formulation at 1.75 lb ai/A; and (ii) the 25% WP at 1-1.5 lb ai/A plus 4-6 gallons of summer oil. Only ground application data are needed for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. Tests must be conducted in CA(100% cling, 34% freestone), MI(4%), NJ(5%) or PA(6%), and SC(23%) which collectively accounted for ca. 70% of the 1987 U.S. peach production (Ag. Statistics Board, NASS, USDA., 1988, Annual Crop Statistics).

25. Data depicting ethion residues of concern in or on plums harvested 21 days following the last of three foliar applications, applied during the fruiting period, using the 4% D and a representative EC formulation at 1.75 lb ai/A and plums harvested 45 days following the last of two foliar applications using the 25% WP formulation at 2.5 lb ai/A and the 4% D formulations, both aerial and ground data must be submitted. The tests for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. The tests must be conducted in CA(100%) which accounted for 100% of the 1987 U.S. plum production (Ag. Statistics Board, NASS, USDA., 1988, Annual Crop Statistics).

26. A processing study depicting ethion residues of concern in prunes processed from plums bearing measurable weathered residues. If residues concentrate, an appropriate food additive tolerance must be proposed.

27. Data depicting ethion residues of concern in or on grapes harvested: (i) 15 days following the last of two foliar applications, made during the fruiting season, of the 4% D formulation at 1.2 lb ai/A ; (ii) 30

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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days following a single foliar application of the 25% WP and the 8 lb/gal EC formulation at 2.25 lb ai/A; and (iii) 60 days following the last of multiple applications of the 25% WP and an EC formulation at 1.25 lb ai/A. Only ground application data are needed for the 25% WP tests. For the other formulations, both aerial and ground data must be submitted. Tests must be conducted in CA which accounted for ca. 90% of the 1987 U.S. grape production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88). The adequacy of the food additive tolerance for residues in or on raisins and the need for feed additive tolerances for residues in other processed commodities will be addressed on receipt of the data requested for grapes.

28. Data depicting the ethion residues of concern in or on strawberries harvested 2 days following the last of multiple foliar applications of the: (i) the 4% D at 1.2 lb ai/A and an EC formulation at 1 lb ai/A using aerial and ground equipment; and (ii) the 25% WP at 1 lb ai/A using ground equipment. Tests must be conducted in CA, since this state accounted for ca. 80% of the 1986 U.S. strawberry production (Ag. Statistics Board, NASS, USDA, 1987, Vegetables, 1986 Summary, p. 27).

29. Data depicting ethion residues of concern in or on almond nutmeat and hulls harvested 30 days following a foliar application of an EC formulation at 2.5 lb ai/A in 200 gallons of water/A using ground equipment, and in 15 gallons of water/A using aerial equipment, in separate tests. Tests must be conducted in CA, which accounted for ca. 99% of 1982 U.S. almond production (1982 Census of Agriculture, Vol. 1, Part 51, p. 367).

30. The data requested for walnuts will be translated to chestnuts.

31. The data requested for walnuts will be translated to filberts.

32. Data depicting ethion residues of concern in or on pecan nutmeats harvested at maturity following the last of two foliar applications made during the fruiting period, of an EC formulations at 2.5 lb ai/A, using

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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ground and aerial equipment in separate tests, and of the 25% WP at 2.5 lb ai/A using ground equipment. The second application must be made just prior to husk split. Tests must be conducted in GA(34%) and TX(32%), which accounted for ca. 70% of 1985 U.S. pecan production (Agricultural Statistics, 1986, p. 234).

33. Data depicting ethion residues of concern in or on walnut nutmeat harvested at maturity following the last of two foliar applications made during the fruiting period, of an EC formulation at 2.5 lb ai/A, using ground and aerial equipment in separate tests, and of the 25% WP at 2.5 lb ai/A using ground equipment. The second application must be made just prior to husk split. Tests must be conducted in CA, which accounted for 99% of 1982 U.S. walnut production (1982 Census of Agriculture, Vol. 1, Part 51, p. 368).

34. Data depicting ethion residues of concern in or on corn grain harvested 50 days after application of a representative EC at 1 lb ai/A using aerial equipment. Tests must be conducted in IL(17%) or IA(18%), IN(9%) or OH(5%), MN(9%), NE(11%), and TX(2%), which collectively accounted for ca. 75% of 1987 U.S. corn grain production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

35. Data depicting ethion residues of concern in or on crude and refined oil, starch, grits, meal, flour and grain dust processed from corn grain bearing measurable, weathered residues. It is recommended that an exaggerated application rate be used to assure the presence of measurable residues in the raw agricultural commodity. If the data indicate a potential for concentration, the registrant must propose an appropriate food/feed additive tolerance.

36. Data depicting ethion residues of concern or on sorghum grain harvested 30 days after the last of three applications, made at 4-day intervals, of the 25% WP and a representative EC at 0.5 lb ai/A. Only ground application data are needed for the 25% WP tests. For the EC formulation, both aerial and ground data must be submitted. Tests must be conducted in KS(37%), NE(15%) and TX(23%) which collectively accounted for ca. 75% of 1987 U.S. sorghum production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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37. Data depicting the potential for concentration of residues in or on flour, starch and grain dust processed from sorghum grain bearing measurable, weathered residues. If the data indicate the potential for concentration of residues, the registrant must propose an appropriate food/feed additive tolerance.

38. Data depicting ethion residues of concern in or on corn fodder harvested 50 days after the last of several foliar applications of a representative EC at 1 lb ai/A using ground and aerial equipment, in separate tests. Tests must be conducted in IL(17%) or IA(18%), IN(9%) or OH(5%), MN(9%), NE(11%), and TX(2%), which collectively accounted for ca. 75% of 1987 U.S. corn production (Agricultural Statistics Board, NASS, USDA, 1988, Crops Database, 1/88). Also, the feeding restriction imposed on fodder is impractical and unenforceable; therefore, it should be removed from the label.

39. Data depicting ethion residues of concern in or on sorghum forage and fodder harvested 30 days after the last of three applications made at 4-day intervals of the 25% WP and a representative EC at 0.5 lb ai/A, in separate tests. Only ground application data are needed for the 25% WP tests. For the EC formulation, both aerial and ground data must be submitted. Tests must be conducted in KS(37%), NE(15%) and TX(23%) which collectively accounted for ca. 75% of 1987 U.S. sorghum production (Annual Crop Statistics, Jan. 1988, Ag. Statistics Board, NASS, USDA). A tolerance for residues in or on fodder must be proposed. Alternatively, a label restriction prohibiting feeding of fodder to livestock may be imposed.

40. Data depicting ethion residues of concern in or on cottonseed harvested at maturity following the last of multiple applications of the 4% D and an EC formulation at 1.6 and 1.5 lb ai/A, respectively, applied using ground and aerial equipment, in separate tests, and the 25% WP at 1.5 lb ai/A applied with only ground equipment. The final application must be made just prior to boll opening. Tests must be conducted in CA(25%), MS(12%) and TX(31%) which collectively accounted for ca. 70% of 1985 U.S. cottonseed production (Agricultural Statistics, 1986, p. 108).

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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41. Data depicting the potential for concentration of ethion residues of concern in cottonseed hulls, crude oil, meal, refined oil and soapstock processed from cottonseed bearing measurable, weathered residues. If the data indicate a potential for concentration of residues in any processed commodity, an appropriate food/feed additive tolerance must be proposed.

42. The registrant must submit current specimen labels in English and appropriate supporting residue data from tests conducted in those countries specified on the labels. The registrant must propose a maximum number of applications per season or a total seasonal use rate. The requested data must reflect this maximum number.

43. On receipt of the data requested in the sections entitled "Qualitative Nature of the Residue in Animals", and "Magnitude of the Residue in Plants" the established tolerances for residues in animal products will be assessed and additional feeding studies may be required.

44. The Agency is now imposing the additional requirement of a tea brewing study. This study must be designed such that the percent reduction in residues of concern during the brewing process can be determined. Tea used in the brewing study must bear measurable, weathered residues at levels as close to the established tolerance as possible. Studies depicting the degradation of ethion residues in transit and storage are required for the following commodities: apples, grapes, melons, tomatoes, dry and succulent beans, strawberries, plums, peaches, oranges, cucumbers, squash, peppers, onions, and tea. Samples must be analyzed at harvest, and at fixed intervals thereafter. Commodities must be kept under conditions of commercial storage and shipment for the minimum and maximum time that each commodity would be in storage or transit between harvest and sale to the consuming public. Information regarding the average and range of conditions and length of commercial storage must be adequately documented. Studies may be terminated when the maximum practical length of storage following harvest has elapsed or when it can be statistically determined that average levels at three consecutive time points have reached the limits of detection for all

TABLE A. GENERIC DATA REQUIREMENTS FOR ETHION.

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
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residues of concern. Due to the complexity of this data requirement, the registrant is urged to submit a protocol for Agency review prior to initiating studies. Also, raw agricultural commodities (RACs) bearing measurable weathered residues at or near the tolerance level must be processed as described below. Residues of concern must be determined in both the RAC and the final food form, as consumed. These data may be used in conjunction with the degradation studies required above and other required and previously submitted processing data to permit more realistic estimates of potential short-term dietary intake of residues of ethion.

Washing - Apples, Grapes, Tomatoes, Strawberries, Plums, Peaches, Cucumbers, Peppers, Oranges
 Cooking - Apples, Grapes, Tomatoes, Dry and Succulent Beans, Peaches, Squash, Peppers, Onions
 Peeling - Melons

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Pattern	Use	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.130 Environmental Fate							
DEGRADATION STUDIES - LAB:							
161-1 Hydrolysis	PAIRA	A,B,F,H	Partial		00155507	Yes ^{1/}	12 Months
PHOTODEGRADATION:							
161-2 In Water	PAIRA	A,B	No			Yes	12 Months
161-3 On Soil	PAIRA OR TCAL	A,B	No			Yes	12 Months
161-4 In Air	PAIRA OR TCAL	A,B	No			Yes	12 Months
METABOLISM STUDIES - LAB:							
162-1 Aerobic Soil	PAIRA	A,B,F,H	Yes		00155510	No	
162-2 Anaerobic Soil	PAIRA OR TCAL	A,B,	No			Yes	24 Months

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Pattern	Use No, Partially	Does EPA Have Data to Satisfy This Require- ment? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.130 Environmental Fate (continued)							
<u>METABOLISM STUDIES - LAB:</u>							
162-3 Anaerobic Aquatic	PAIRA OR TGAI					No ^{2/}	
162-4 Aerobic Aquatic	PAIRA OR TGAI					No ^{2/}	
<u>MOBILITY STUDIES:</u>							
163-1 Leaching and Adsorption/Des.	PAIRA	A, B, F, H	No			Yes ^{3/}	12 Months
163-2 Volatility (Lab)	TEP	A, B, F	No			Yes	12 Months
163-3 Volatility (Field)	TEP	A, B, F	No			Reserved ^{4/}	
<u>DISSIPATION STUDIES-FIELD:</u>							
164-1 Soil	TEP	A, B, H	No			Yes	24 Months
164-2 Aquatic (Sediment)	TEP					No ^{2/}	

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Pattern	Use	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.130 Environmental Fate (continued)							
<u>DISSIPATION STUDIES-FIELD:</u>							
164-3 Forestry	TEP					No ^{2/}	
164-4 Combination and Tank Mixes	TEP					No ^{5/}	
164-5 Soil, Long-Term	TEP	A, B, H		No		Reserved ^{6/}	
<u>ACCUMULATION STUDIES:</u>							
165-1 Rotational Crops (Confined)	PAIRA	A, B		No		Yes	24 Months
165-2 Rotational Crops (Field)	TEP	A, B		No		Reserved ^{7/}	
165-3 Irrigated Crops	TEP					No ^{2/}	
165-4 In Fish	PAIRA/ TCAI	A, B		Yes	00153553 00155515	No	
165-5 In Aquatic Non-Target Organisms	TEP					No	

Table A
Generic Data Requirements for Ethion

158.130 Environmental Fate Footnotes:

- 1/ This data requirement is satisfied for pH 5 and pH 7. However, due to the fact that the borate buffer may have caused ethion to degrade or reacted with its degradates. The registrant has the option of addressing this concern in a written explanation or the pH 9 experiment should be repeated using another buffer.
- 2/ Not required because ethion has no aquatic or forestry uses.
- 3/ Batch equilibrium (adsorption/desorption) is required for the domestic outdoor and greenhouse uses.
- 4/ This study may be required, depending on the results of the laboratory volatility study.
- 5/ This data requirement is not being imposed at this time.
- 6/ This data may be required, depending on the results of the field dissipation studies.
- 7/ This data may be required, depending on the results of the confined rotational crop study.

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation 3(c)(2)(B)?	Must Additional Data Be Submitted Under FIFRA Section For Data Submission	Timeframe
<u>158.390 - Reentry Protection:</u>						
132-1 Foliar Dissipation	TEP	A,B,F,H	No		Yes	24 Months
132-1(2) Soil Dissipation	TEP	A,B,F,H	No		Yes	24 Months
133-3 Dermal Exposure	TEP	A,B,F,H	No		Yes	24 Months
133-4 Inhalation Exposure	TEP	A,B,F,H	No		Yes	24 Months
<u>158.75 - Applicator Exposure Monitoring:</u>						
231 Estimation of dermal exposure at outdoor sites.	TEP	A,B,F,H	No		Yes	24 Months
323 Estimation of inhalation exposure at outdoor sites.	TEP	A,B,F,H	No		Yes	24 Months
333 Estimation of dermal exposure at indoor sites.	TEP	A,B,F,H	No		Yes	24 Months

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>158.75 & 158.390 - Non-Occupational Post-Application Exposure Monitoring:</u>						
133-3 Dermal Exposure	TEP	A, B, F, H	No		Yes	24 Months
133-4 Inhalation Exposure	TEP	A, B, F, H	No		Yes	24 Months
232, 234						
132-1 Foliar Dissipation	TEP	A, B, F, H	No		Yes	24 Months

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>158.135 Toxicology:</u>						
<u>ACUTE TESTING:</u>						
81-1 Acute Oral Rat	TGAI	A	Yes	00157590	No	
81-2 Acute Dermal	TGAI	A	Yes	00157590	No	
81-3 Acute Inhalation - Rat	TGAI	A	Yes	00163159	No	
81-4 Eye Irritation -Rabbit	TGAI	A	Yes	00157590	No	
81-5 Dermal Irritation -Rabbit	TGAI	A	Yes	00157590	No	
81-6 Dermal Sensitization -Guinea Pig	TGAI	A	Yes	00157590 00141205	No	
81-7 Acute Delayed Neurotoxicity - Hen	TGAI	A	Yes	00158376	No	
<u>SUBCHRONIC TESTING:</u>						
82-1 90-Day Feeding						No ^{2/}
- Rodent	TGAI	A	No			
- Non-rodent	TGAI	A	Yes	40773301	No	

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>158.135 Toxicology: (Cont.)</u>						
82-1 21-Day Dermal	TGAI	A	Yes	00155498 00155499	No	
82-3 90-Day Dermal	TGAI	A	No		No ³ /	
82-4 90-Day Inhalation	TGAI	A	No		No ³ /	
82-5 90-Day Neurotoxicity	TGAI	A	No		No ¹ /	
<u>CHRONIC TESTING:</u>						
83-1 Chronic Toxicity -						
Rodent	TGAI	A	Yes	00148991	No	48 Months
Non-rodent	TGAI	A	No		Yes	
83-2 Oncogenicity Study -						
Rat	TGAI	A	Yes	00148991	No	
Mouse	TGAI	A	Yes	00148989	No	
83-3 Teratogenicity						
Rat	TGAI	A	Yes	00131852	No	
Rabbit	TGAI	A	Yes	00131853	No	
83-4 Reproduction	TGAI	A	Yes	00148990	No	

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.135 Toxicology: (Cont.)						
<u>MUTAGENICITY TESTING:</u>						
84-2 Gene Mutation	TGAI	A	Yes	00144351	No	
84-2 Chromosomal Aberration	TGAI	A	No		Yes	12 Months
84-2 Other Mechanism of Mutagenicity	TGAI	A	No		Yes	12 Months
<u>SPECIAL TESTING:</u>						
85-1 General Metabolism	PAI or TGAI	A	Yes	00155871 00155872 00155873	Reserved ^{4/}	

1/ Since an acute neurotoxicity did not show neurotoxic effects, a 90-day delayed neurotoxicity study is not required.

2/ Since an acceptable chronic rat study is available, the requirement of a subchronic rat study is waived.

3/ Not required under the registered use patterns.

4/ These studies are currently under review by the Agency. Registrant will be notified if additional studies are required.

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Pattern	Use	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.490 - Wildlife and Aquatic Organisms</u>							
<u>Avian and Mammalian Testing</u>							
71-1 -Avian Acute Oral Toxicity	TGAI						
- Upland game bird		A, B, H	Yes		00146309 00146310	No	
71-2 - Avian Dietary LC50	TGAI		Yes		00022023	No	
71-3 - Wild Mammal Toxicity	TGAI	A, B, H	No			No	
71-4 - Avian Reproduction			No			Yes ¹ /	24 Months
71-5 - Simulated and Actual Field Testing - Birds and Mammals			No			No	
<u>Aquatic Organism Testing</u>							
72-1 - Freshwater Fish LC50	TGAI	A, B, H	Yes		00003503	No	
72-2 - Freshwater Invertebrate LC50	TGAI	A, B, H	Yes		00003503	No	

Table A
Generic Data Requirements for Ethion

(cont'd)

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.490 - Wildlife and Aquatic Organisms</u>						
<u>Aquatic Organism Testing</u> (continued)						
72-3 - Estuarine and Marine Organisms LC50	TGAI	A,B,H	Yes	00155517 00155516 00155518	No	
72-4 - Fish Early Life Stage and Invertebrate Life Cycle	TGAI	A,B,H	No		Yes ^{2/}	24 Months
72-5 - Fish Life Cycle	TGAI	A,B,H	No		Reserved ^{3/}	
72-6 - Aquatic Organisms Accumulation	TGAI	A,B,H	Yes	00153553	No	
72-7 - Simulated or Actual Field Testing						
-Aquatic Organisms	TGAI	A,B,H	Yes		Reserved ^{3/}	

Table A
Generic Data Requirements for Ethion (cont'd)

§ 158.490-Wildlife and Aquatic Organisms Footnotes:

- 1/ This study is required because of ethion's persistence in the environment, expected residue levels on avian food, accumulation in plant and animal tissue, and the exposure potential to birds.
- 2/ These studies are required because ethion is persistent in water, bioaccumulates in fish tissue, acutely toxic, and there is a high potential exposure.
- 3/ These studies may be required pending the environmental fate data on field dissipation and the results of a fish early life stage and daphnid life-cycle study.

Table A
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.155 Nontarget Insects</u>						
<u>NONTARGET INSECT TESTING - POLLINATORS</u>						
141-1 - Honey Bee Acute Contact LD50	TGAI	A,B	Yes	00036935	No	
141-2 - Honey Bee - Toxicity of residues on foliage	TEP	A,B	No		No ^{1/}	
141-4 - Honey Bee Subacute Feeding Study	Reserved ^{2/}					
141-5 - Field Testing for pollinators	TEP	A,B	No ^{1/}			
<u>NONTARGET INSECT TESTING - AQUATIC INSECTS</u>						
142-1 - Acute Toxicity to Aquatic Insects	Reserved ^{3/}					
142-2 - Aquatic Insect Life Cycle Study	Reserved ^{3/}					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved ^{3/}					
<u>NONTARGET INSECT TESTING - PREDATORS AND PARASITES</u>						
					Reserved ^{3/}	

Table A
Generic Data Requirements for Ethion
(cont'd)

§158.155 - Nontarget Insects Footnotes:

- 1/ As Data from the acute contact test indicate low toxicity; no further testing is required.
- 2/ This requirement is reserved pending development of test methodology.
- 3/ This requirement is reserved pending Agency decision as to whether the data requirement should be established.

Table B
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>158.135 Toxicology:</u>						
81-1 Acute Oral Rat	MP ¹ /	All	Yes	00157590	No	
81-2 Acute Dermal	MP ¹ /	All	Yes	00157590	No	
81-3 Acute Inhalation - Rat	MP ¹ /	All	Yes	00163159	No	
81-4 Eye Irritation -Rabbit	MP ¹ /	All	Yes	00157590	No	
81-5 Dermal Irritation -Rabbit	MP ¹ /	All	Yes	00157590	No	
81-6 Dermal Sensitization -Guinea Pig	MP ¹ /	All	Yes	00157590 00141205	No	

1/ Data derived from acute toxicity tests conducted on the TGA1 will satisfy this requirement.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR ETHION MANUFACTURING-USE PRODUCTS.

Data Requirement	Test Substance	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
<u>40 CFR §158.155-190 Product Chemistry</u>					
<u>Product Composition</u>					
61-1. Product Composition	MP	Partially	Reg. Jackets 00132773	Yes ¹	12 months
61-2. Beginning Materials & Production or Formulation Process	MP	Partially	00157088	Yes ²	12 months
61-3. Formation of Impurities	MP	Partially	00132773	Yes ³	12 months
<u>Analysis and Certification of Product Ingredients</u>					
62-1. Preliminary Analysis	MP	Partially	00132773	Yes ⁴	12 months
62-2. Certified Limits	MP	Partially	Reg. Jackets	Yes ⁵	12 months
62-3. Enforcement Analytical Methods	MP	Partially	00132773	Yes ⁶	12 months
<u>Physical and Chemical Characteristics</u>					
63-2. Color	MP	Yes	00132773	No	12 months
63-3. Physical State	MP	Yes	00132773	No ⁷	12 months
63-4. Odor	MP	Partially	00132773	Yes ⁷	12 months
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	00132773	Yes ⁷	12 months
63-12. pH	MP	Partially	00132773	Yes ⁷	12 months
62-14. Oxidizing or Reducing Action	MP	Partially	00132773	Yes ⁷	12 months
62-15. Flammability	MP	Partially	00132773	Yes ⁷	12 months
63-16. Explosibility	MP	Partially	00132773	Yes ⁷	24 months
63-17. Storage Stability	MP	Partially	00132773	Yes ⁷	12 months
63-18. Viscosity	MP	Partially	00132773	Yes ⁷	12 months
63-19. Miscibility	MP	Partially	00132773	Yes ⁷	12 months
63-20. Corrosion Characteristics	MP	Partially	00132773	Yes ⁷	24 months
<u>Other Requirements:</u>					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

TABLE B. (Continued).

1. For the FMC 88% T (279-2280) and the Aceto 95% T (2749-293), new CSFs must be provided with the chemical name and nominal concentration of the active ingredient and each impurity of toxicological significance associated with the active ingredient or present in any sample at a level $\geq 0.1\%$ (w/w). For the Cheminova 94% T (4787-10), the nominal concentration of the active ingredient must be provided so that the Agency may calculate certified limits according to 40 CFR 158.175(b)(2). Also, if additional impurities of toxicological concern or present at $\geq 0.1\%$ (w/w) are found in the tests required under 62-1 (preliminary analysis) for the Cheminova 94% T (4787-10), a new CSF reflecting such impurities will be required.
2. For the Aceto 95% T (EPA Reg. No. 2749-293) the following information must be provided: a description of the procedures used to assure consistent composition of the substance produced (quality control methods), the name and address of the producer of each beginning material and information concerning the composition of each, the nature of the process (batch or continuous), the proportions of beginning materials and the order in which they are added, the duration of each step of the process and a flow chart of the chemical equations. For the Cheminova 94% T (EPA Reg. No. 4787-10), the name and address of the producer of each beginning material must be provided.
3. For the Aceto 95% T (EPA Reg. No. 2749-293) a discussion regarding the origin of the following potential impurities must be provided: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. For the FMC 88% T (EPA Reg. No. 279-2280) and the Cheminova 94% T (EPA Reg. No. 4787-10) discussion of the possible degradation of ingredients in the product after production, and post-production reactions between the ingredients in these products is required.
4. For the analytical method used for sample analysis of the FMC 88% T (MRID 00132773), statements of accuracy must be submitted. Also, the FMC and Cheminova products must be analyzed (using validated methods) for all impurities discussed under 61-3 (MRID Nos. 00132773 and 00157088) that are of toxicological concern or may be present at $\geq 0.1\%$ (w/w). For the Aceto 95% T (EPA Reg. No. 2749-293) five or more representative batch samples must be analyzed for the amount of active ingredient and each impurity present at 0.1% or greater. Complete and detailed descriptions of the methods used for sample analysis must be submitted,

TABLE B. (Continued).

including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which analysis is conducted along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided.

5. For the FMC 88% T and the Aceto 95% T, updated CSFs (on EPA Form 8570-4) must be provided in which upper limits are provided for each toxicologically significant impurity associated with the active ingredient and found to be present in any sample of the product. Limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amount of ingredient used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Also, if the data required under 62-1 (preliminary analysis) for the Cheminova 95% T reveal additional impurities of toxic concern, a new CSF with upper limits for such impurities must be provided.
6. For the Aceto 95% T, analytical methods which are suitable for enforcement purposes must be provided for each impurity that is determined to be toxicologically significant. Suitability for enforcement purposes shall be determined from validation studies of method accuracy and precision submitted by the registrant. Information regarding the accuracy of methods submitted for analysis of impurities in the FMC 88% T (MRID 00132773) must be submitted. Also, if additional impurities of toxicological concern are found in the FMC 88% T or the Cheminova 94% T in the tests required under 62-1 (preliminary analysis), methods suitable for enforcement of certified limits for such impurities will be required.
7. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted for the physical and chemical characteristics of manufacturing-use products. All of these data except for color, physical state, melting point and dissociation constant are required for the Aceto 95% T (EPA Reg. No. 2749-293). In addition, data are required on the following specific physical/chemical characteristics for the products indicated by EPA Reg. Nos. in parentheses: descriptive definition of odor (4787-10); pH (279-2280) and temperature used to determine pH (4787-10); oxidizing or reducing action (279-2280 and 4787-10); viscosity (method used to determine 4787-10); miscibility (4787-10 and temperature for determination of 279-2280); and methods used to determine corrosion characteristics (279-2280 and 4787-10).

Table C
Product-Specific Data Requirements for End-Use Products Containing Ethion

Data Requirement	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, Bibliographic Citation No., or Partially)	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Data Submission
<u>Part 158, Subpart C, Product Chemistry</u>				
<u>Product Identity and Composition</u>				
61-1 - Product Identity and Composition	EP	No ¹ /	Yes ² /	12 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	No ¹ /	Yes ³ /	12 Months
61-3 - Discussion of Formation of Impurities	EP	No ¹ /	Yes ⁴ /	12 Months
<u>Analysis and Certification of Product Ingredients</u>				
62-1 - Preliminary Analysis of Product Samples	EP	No ¹ /	Yes ⁵ /	12 Months
62-2 - Certification of Ingredient Limits	EP	No ¹ /	Yes ⁶ /	12 Months
<u>Physical and Chemical Characteristics</u>				
63-7 - Density, Bulk Density, or Specific Gravity	EP	No ¹ /	Yes ⁷ /	12 Months
63-12 - pH	EP	No ¹ /	Yes ^{7.8} /	12 Months
63-15 - Flammability	EP	No ¹ /	Yes ^{7.9} /	12 Months

Table C
Product-Specific Data Requirements for End-Use Products Containing Ethion

Part 158, Subpart C, Product Chemistry Footnotes

- 1/Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.
- 2/The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient in each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned code numbers.
- 3/Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.
- 4/A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.
- 5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. Required for products produced by an integrated system.
- 6/Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at $\geq 0.1\%$ (w/w) and each "toxicologically significant" impurity present at $< 0.1\%$ (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimates based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA Form 857 Rev. 2-85.
- 7/Density or specific gravity, pH, and flammability information must be submitted for each product as part of the Confidential Statement of Formula. Other physicochemical characteristics (color, physical state, odor, melting point, solubility, vapor pressure, dissociation constant, partition coefficient, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, are not required at this time.
- 8/Data required if the test substance is dispersible in water.
- 9/Data required if the product contains combustible liquids.

Table C
Generic Data Requirements for Ethion

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>158.135 Toxicology:</u>						
81-1 Acute Oral Rat	EP	All	No		Yes	24 Months
81-2 Acute Dermal	EP	All	No		Yes	24 Months
81-3 Acute Inhalation - Rat	EP	All	No		Yes	24 Months
81-4 Eye Irritation -Rabbit	EP	All	No		Yes	12 Months
81-5 Dermal Irritation -Rabbit	EP	All	No		Yes	12 Months
81-6 Dermal Sensitization -Guinea Pig	EP	All	No		Yes	12 Months

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. **PRODUCT NAME** - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. **COMPANY NAME AND ADDRESS** - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. **NET CONTENTS** - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. **EPA REGISTRATION NUMBER** - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. **EPA ESTABLISHMENT NUMBER** - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. **INGREDIENTS STATEMENT** - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

<u>Size of Label on Front Panel in Square Inches</u>	<u>Signal Word Minimum Type Size All Capitals</u>	<u>"Keep Out of Reach of Children" Minimum Type Size</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.56(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)].

SUMMARY-3

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY
Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of Part 152, Subpart I. You will be notified of the Agency's classification decision.

SUMMARY-4

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv))

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

SUMMARY-5

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.
[40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following of heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

Chapter I--Environmental Protection Agency

\$156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

- (i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;
- (ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;
- (iii) The net contents as prescribed in paragraph (d) of this section;
- (iv) The product registration number as prescribed in paragraph (e) of this section;
- (v) The producing establishment number as prescribed in paragraph (f) of this section;
- (vi) An ingredient statement as prescribed in paragraph (g) of this section;
- (vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;
- (viii) The directions for use as prescribed in paragraph (i) of this section; and
- (ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

- (A) Be set in 6-point or larger type;
- (B) Appear on a clear contrasting background; and
- (C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

- (A) "Contains all natural ingredients";
- (B) "Among the least toxic chemicals known"
- (C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***,", "Distributed by ***,", or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD ₅₀	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC ₅₀	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD ₅₀	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed (inhaled or absorbed through skin). Do not breathe vapor (dust) or spray mist). Do not get in eyes, on skin, or on clothing (Front panel statement of practical treatment required.).	Corrosive, causes eye and skin damage (or skin irritation). Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed (inhaled or absorbed through the skin). Avoid breathing vapors (dust or spray mist). Avoid contact with skin (eyes or clothing). [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or

damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD₅₀ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC₅₀ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD₅₀ of 100 mg/kg or less, or a subacute dietary LC₅₀ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repackaging for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification.

(A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978; amended at 53 FR 15952, May 4, 1988]

PHYSICAL/CHEMICAL HAZARDS

<u>Criteria</u>	<u>Required Label Statement</u>
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. <u>All Other Pressurized Containers</u>	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDESHeading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused ^{1/} , dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

^{1/} Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. **CONTENT OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

BIBGUIDE-2

- a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.
- b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

MRID

Citation

- 00022023 Anon. (1968) Phostoxin as a sanitation control measure. [Without Title] 13(7):274-277. (Also in unpublished submission received on unknown date under 6F0508; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:090598-B)
- 00034311 Stanovick, R.P.; Ursel, J.; Martin, N. (1964) Determination of Ethion Residues in or on Field-Treated Grain Sorghum. Method M-1343 dated Mar 19, 1964. (Unpublished study received Apr 20, 1964 under 279-1254; submitted by FMC Corp., Philadelphia, Pa.; CDL:002322-B)
- 00034468 FMC Corporation (19??) Blank and Recovery and Analytical Data. (Unpublished study received Apr 28, 1964 under 279-1254; CDL:002323-C)
- 00034874 FMC Corporation (1962) Ethion Residues on Strawberries Treated with Ethion 4 Miscible: R-544. (Unpublished study received May 14, 1962 under 279-1254; CDL:002320-A)
- 00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ? : UC, Cooperative Extension. (Leaflet 2287; published study.)
- 00073053 Niagara Chemical (1966) Data Establishing That Ethion May Reasonably Be Expected To Be a Component of Dried Tea Leaves and Dried Tea Concentrates. (Compilation; unpublished study received Oct 13, 1966 under 1H0000; CDL:221561-C)
- 00073062 Niagara Chemical (1960) [Ethion Residues in or on Citrus]. (Compilation; unpublished study received Apr 28, 1964 under PP0316; CDL:092597-A)
- 00073082 Niagara Chemical (1957) Time Studies To Show Decrease of Residue with Time. (Unpublished study received Aug 1, 1958 under PP0189; CDL:090217-P)
- 00073083 Niagara Chemical (1958) Residues of Ethion on and in Field Treated Crops at Harvest Time. (Unpublished study received Aug 1, 1958 under PP0189; CDL:090217-Q)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

MRID

Citation

- 00073085 Niagara Chemical (19??) Time Studies To Show Change of Residues with Time. (Unpublished study received Dec 18, 1958 under PP0192; CDL:090220-B)
- 00073094 Niagara Chemical (1961) The Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: [Ethion]. (Unpublished study received Apr 1, 1961 under PP0316; CDL:090336-B)
- 00073095 Niagara Chemical (1960) The Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: [Ethion!]. (Unpublished study received Jan 3, 1961 under PP0308; CDL:090328-A)
- 00073100 FMC Corporation (19??) Rresults of Tests the Amount of Residue Remaining and Description of Analytical Method: Residue Analysis of Ethion Using MCMG Analytical Procedure. Undated method. Unpublished study received Aug. 1, 1966 under 7F0519; CDL: 092005-E)
- 00073105 Niagara Chemical (19??) Colorimetric Method for the Determination of Ethion Residues on Crops. (Unpublished study received on unknown date under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:119615-A)
- 00073121 Niagara Chemical (1958) Report of Residue Determinations of Ethion in Onions. (Unpublished study received May 22, 1958 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:127165-A)
- 00073132 Niagara Chemical (1961) Ethion Residue Data: Field Corn. (Unpublished study received Mar 1, 1961 under unknown admin. no.; submitted by FMC Corp., Philadelphia, Pa.; CDL:119608-A)
- 00073133 Niagara Chemical (1959) Ethion Residues on Tomatoes. (Unpublished study received Feb 2, 1959; Apr 20, 1959 under PP0214; CDL: 092492-A)
- 00073138 Niagara Chemical (1960) Ethion Residue Analysis of Liver Samples from Ethion Cow Feeding Study. (Unpublished study received Mar. 10, 1970 under PP0253; CDL: 092529-D)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

<u>MFID</u>	<u>Citation</u>
00073143	FMC Corporation (1959) Results of Tests on the Amount of Residue Remaining and Description of Analytical Method: [Ethion]. Includes method entitled: Infrared determination of ethion residues on and in citrus fruits. (Unpublished study received Mar 10, 1960 under PP0253; CDL:090279-A)
00073144	Bowman, J.S. 1960 Final Report: Subacute Feeding - Dairy Animals. (Unpublished study received Mar. 10, 1960 under PP0253; submitted by FMC Corp., Middleport, N.Y. CDL:90279-B)
00073145	FMC Corporation (1959) [Residue Data for Ethion in Several Fruits]. (Unpublished study received Feb. 23, 1960 under PP0246; CDL: 090273-A)
00073152	Niagara Chemical (1958) [Residue Data for Ethion in Fruit]. (Unpublished study received May 1, 1959 under PP0214; CDL:090241-G)
00073153	Shuttleworth, J.M.; Burt, J.E.; Gruenauer, M.H.; et al. (1971) Residue Determinations of Ethion and Its Oxygen Analogs in Milk and Cow Tissue: M-2808. (unpublished study received Dec 12, 1969 0F0920; submitted by FMC Corp., Middleport, N.Y.; CDL: 093218-A)
00073158	Hinstridge, P.A.; Yaffe, J.; Cardenas, B.; et al. (1970) Ethion Residues on Cottonseed--Process Study: R-1156. (Unpublished study received May 28, 1970 under 0F0920; prepared in cooperation with Texas A & M Univ., submitted by FMC Corp., Middleport, N.Y.; CDL:091575-C)
00073160	FMC Corporation (1967) Results of Tests of the Amount of Residues Remaining and Description of Analytical Methods: [Ethion!]. Includes methods dated Apr 3, 1957 and Feb 28, 1958. (Unpublished study received May 28, 1970 under 0F0920; CDL:091575-E)
00073161	Shuttleworth, J.M.; Bowin, R.J.; Radaker, L.; et al. (1969) Determination of Ethion Residues in Eggs and Poultry Tissues: M-2548. (Unpublished study received May 28, 1970 under 0F0920; submitted by FMC Corp., Middleport, N.Y.; CDL:091575-G)
00073162	FMC Corporation (1967) Results of Tests of the Amount of Residues Remaining and Description of Analytical Methods: [Ethion]. (Unpublished study received May 27, 1970 under 0F0918; CDL: 091573-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

MRID

Citation

- 00073173 Shuttleworth, J.M.; Arnold, R.W.; Gruenauer, M.H.; et al. (1971) Determination of Ethion, Ethion Monooxon and Ethion Dioxon Residues in Corn Forage: M-2922. Includes method dated Aug 31, 1971. (Unpublished study received Sep 9, 1971 under 1F1104; submitted by Niagara Chemical, Div. of FMC Corp., Los Fresnos, Tex.; CDL:090869-A)
- 00073175 Niagara Chemical (1970) Results of Tests of the Amount of Residues Remaining and Description of Analytical Methods: [Ethion]. (Unpublished study received Sep 9, 1971 under 1F1104; CDL:090869-C)
- 00073189 FMC Corporation (1960) Blank and Recovery and Analytical Data. (Compilation; unpublished study received Mar 23, 1960 under unknown admin. no.; CDL:124930-A)
- 00073195 FMC Corporation (19??) Ethion--Nectarine. (Unpublished study received Jan 7, 1967 under 7F0519; CDL:090614-E)
- 00073806 Niagara Chemical (1962) [Residues of Ethion in Fruit after Drying]. (Compilation; unpublished study received Mar 5, 1962 under PP0351; CDL:092635-C)
- 00073808 FMC Corporation (1958) [Residues of Ethion: Peaches, Cotton and Various Crops]. (Compilation; unpublished study received May 16, 1958 under 279-1254; CDL:119616-A)
- 00109285 FMC Corp. (1972) [Residues of Ethodan in Oranges, Apples and Other Crops]. (Compilation; unpublished study received Jul 27, 1982 under 279-2280; CDL:247912-A)
- 00131853 Hoberman, A.; Christian, M.; Christian, G.; et al. (1983) Teratogenic Potential of Ethion Technical Administered Orally via Stomach Tube to New Zealand White Rabbits: (Segment II Evaluation): 106-002; A82-679. Final rept. (Unpublished study received Aug 17, 1983 under 279-2280; prepared by Argus Research Laboratories, Inc., submitted by FMC Corp., Philadelphia, PA; CDL:251005-B)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

<u>MRID</u>	<u>Citation</u>
00131852	Hoberman, A.; Christian, M.; Christian, G. (1983) Teratogenic Potential of Ethion Technical in Pregnant Crl:COBS CD (SD) BR Charles River Rats: Project 106-001; A81-646. Final rept. (Unpublished study received Aug 17, 1983 under 279-2280; prepared by Argus Research Laboratories, Inc., submitted by FMC Corp., Philadelphia; PA; CDL:251005-A)
00132773	FMC Corp. (1983) Product Chemistry for Ethion: Technical and Manufacturing-Use Product. (Compilation; unpublished study received Nov 10, 1983 under 279-2280; CDL:251799-A)
00141205	Freeman, C. (1984) Skin Sensitization of Ethion Technical in Guinea Pigs: Study No. A83-1108. Unpublished study prepared by FMC corp. 36 p.
00144351	Haworth, S. (1984) Salmonella/Mammalian-microsome Plate Incorporation Mutagenicity Assay (Ames Test): Study No. T2266-501. Unpublished study prepared by Microbiological Associates. 36 p.
00146309	Beavers, J. (1984) An Acute Oral Toxicity Study in the Bobwhite with FMC 1240: Final Report: Wildlife International Ltd. Project No.: 104-155. Unpublished study prepared by Wildlife International Ltd. 29 p.
00146310	Beavers, J. (1984) An Acute Oral Toxicity Study in the Mallard with FMC 1240: Final Report: Wildlife International Ltd. Project No. 104-156A. Unpublished study prepared by Wildlife International Ltd. 29 p.
00148989	Morrow, L. (1985) Lifespan Oncogenicity Study in Mice Utilizing Ethion (FMC 1240) Technical: American Biogenics Corporation Study No. 410-0867. Unpublished FMC Study No. A82-726 prepared by American Biogenics Corp. 3210 p.
00148990	Enloe, P.; Salamon, C. (1985) Three-generation Reproduction Study in Albino Rats with Ethion (FMC 1240) Technical: American Biogenics Corporation Study No. 450-0868. Unpublished FMC Study No. A82-722 prepared by American Biogenics Corp. 2627 p.
00148991	Morrow, L. (1985) Twenty-four Month Combined Chronic Oral Toxicity and Oncogenicity Study in Rats Utilizing Ethion (FMC 1240) Technical: American Biogenics Corporation Study No. 410-0866. Unpublished FMC Study No. A82-725 prepared by American Biogenics Corp. 3858 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

MRID

Citation

- 00153160 Martin, F. (1985) Determination of Ethion, Ethion Monoxon, Ethion Dioxon Residues in/on Cucurbits (Cucumber, Melon, Squash): Project No. G237. Unpublished study prepared by FMC Corp. 27 p.
- 00153553 Forbis, A.; Georgie, L.; Bunch, B. (1985) Uptake, Depuration and Bioconcentration of :Carbon 14:-Ethion by Bluegill Sunfish (*Lepomis macrochirus*): ABC Final Report #32423. Unpublished FMC Corporation's Study No. 237E54E01 prepared by Analytical Bio-Chemistry Laboratories, Inc. 47 p.
- 00155498 Weiner, M. (1985) Twenty-one Day Repeated Dose Dermal Toxicity Study in Rabbits with FMC 1240 Technical (Ethion): Study No. A84-1369. Unpublished study prepared by FMC Corp. 299 p.
- 00155499 Weiner, M. (1985) Twenty-one Day Repeated Dose Dermal Toxicity Study in Male Rabbits with FMC 1240 Technical (Ethion): Study No. A84-1502. Unpublished study prepared by FMC Corp. 274 p.
- 00155504 Martin, F. (1985) Cold Storage Stability of Ethion, Ethion Monoxon, and Ethion Dioxon in/on Various Crops and Soils: P-1296: FMC Study No. 237CSSR01. Unpublished study prepared by FMC Corp. 35 p.
- 00155507 Reynolds, J. (1984) Hydrolysis of Ethion: P-0801: Study No. S 237 83 01. Unpublished study prepared by FMC Corp. 21 p.
- 00155510 Puhl, R.; Conley, J.; Blair, J. (1985) Aerobic/Anaerobic Soil Metabolism of Ethion: Study No. 6015-210. Unpublished FMC Report No. PC-0029 and Study No. 237E21E01 prepared by Hazleton Laboratories America, Inc. 67 p.
- 00155515 Markle, J. (1985) Analysis of :Carbon 14:-Ethion Residues in Bluegill Sunfish and Water: RAN-0168: Study No. 237E54E01. Unpublished study prepared by FMC Corp. 31 p.
- 00155516 Ward, G. (1985) Toxicity Test Report: Acute Toxicity of FMC 1240 Technical to Pink Shrimp (*Penaeus duorarum*): ESE No. 85-322-0200-2130. Unpublished FMC Study No. A84-1192 prepared by Environmental Science and Engineering, Inc. 33 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

<u>MRID</u>	<u>Citation</u>
00155517	Ward, G. (1985) Toxicity Test Report: Acute Toxicity of FMC 1240 Technical to the Atlantic Silverside (<i>Menidia menidia</i>): ESE No. 85-322-0210-2130. Unpublished FMC Study No. A84-1218 prepared by Environmental Science and Engineering, Inc. 32 p.
00155518	Ward, G. (1985) Toxicity Test Report: Acute Toxicity of FMC 1240 Technical to Embryos and Larvae of the Eastern Oyster (<i>Crassostrea virginica</i>): ESE No. 85-322-0300-2130. Unpublished FMC Study No. A85-1762 prepared by Environmental Science and Engineering, Inc. 19 p.
00155580	Miller, P.; Wetters, J.; McKellar, R.; et al. (1986) Residues of Chlorpyrifos and 3,5,6-Trichloro-2-pyridinol in Broccoli, Cabbage and Mustard Greens following Multiple Applications of Lorsban and/or Dursban Insecticides: GH-C 1788. Unpublished study prepared by Dow Chemical U.S.A. 52 p.
00155850	FMC Corp. (19??) The Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used. Unpublished compilation. 347 p.
00155869	Patterson, H. (1985) BTC No. 01030: Evaluation of Ethion Fate and Behavior in/on Oranges: WP507154. Unpublished FMC Report No. PC-0030 and Study No. 237CITM01 prepared by Biological Test Center. 83 p.
00155870	Selim, S. (1985) Analysis of Ethion and Its Metabolites in/on Oranges and Orange Leaves: WP511176. Unpublished FMC Report No. PC-0028 and Study No. 237CIT01 prepared by Biological Test Center. 26 p.
00155871	Selim, S. (1985) Absorption, Distribution and Excretion Studies of Ethion in the Rat: Study No. P00911. Unpublished FMC Report No. PC-0031 and Study No. 237RATM01 prepared by Biological Test Center. 103 p.
00155872	Selim, S. (1985) Rat Blood Kinetics of Ethion following a Single Oral Dose: Study No. P00970. Unpublished FMC Report No. PC-0036 and Study No. 237RATM02 prepared by Biological Test Center. 35 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Ethion Standard

MRID

Citation

- 00155873 Selim, S. (1985) Analysis of Metabolites in Urine of Rats Dosed with Ethion: WP512122: Interim Report: Unpublished FMC Report No. PC-0035 and Study No. 237RATM01 prepared by Biological Test Center. 34 p.
- 00155874 Puhl, R.; Jobsis, C.; Zietlow, D. (1985) Metabolism Study of :Carbon 14:-Labelled Ethion in Lactating Goats: Final Report: Study No. 6124-104. Unpublished FMC Report No. PC-0027 and Study No. 237GOAM01 prepared by Hazleton Laboratories America, Inc. 116 p.
- 00155875 Puhl, R.; Bodden, R.; Zietlow, D. (1985) Poultry Metabolism Study on Ethion: Final Report: Study No. 6124-103. Unpublished FMC Report No. PC-0026 and Study No. 237POUM01 prepared by Hazleton Laboratories America, Inc. 123 p.
- 00157088 Cheminova (1985) Product Chemistry: Ethion Technical. Unpublished study. 87 p.
- 00157590 Cuthbert, J.; Carr, S. (1986) Ethion 95% Technical: Acute Toxicity Tests: IRI Project No. 234117: Report No. 3467. Unpublished study prepared by Inveresk Research International. 54 p.
- 00158376 Roberts, N.; Phillips, C.; Gopinath, C.; et al. (1986) Acute Delayed Neurotoxicity Study with FMC 1240 in the Domestic Hen: FCC 81/851263. Unpublished study prepared by Huntingdon Research Centre Ltd. 64 p.
- 00159983 Barrett, G. (1986) Determination of Ethion, Ethion Monooxon and Ethion Dioxon Residues in/on Field Corn Grain Treated with Ethion Insecticide: Report No. RAN-0172. Unpublished study prepared by FMC Corp. 18 p.
- 00163159 Fieser, S. (1983) Acute Inhalation Toxicity Study in Rats: Ethion Technical (FMC1240): FMC Study No. A83-873: Hazleton No. 104-214: Final Report. Unpublished study prepared by Hazleton Laboratories America, Inc. 40 p.
- 40773301 Bailey, D. E. (1988) 90-Day Subchronic Toxicity Study of Ethion Technical in Dogs (A86-1990). Hazleton Laboratories America, Inc.; HLA Study No. 104-229. June 12, 1988.

IV. FORM APPENDICES

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET		EPA REGISTRATION NO.
PRODUCT NAME		
APPLICANT'S NAME		DATE GUIDANCE DOCUMENT ISSUED
With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:		
☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:		
☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:		
NAME OF OTHER REGISTRANT		
☐ 3. I enclose a completed "Certification of Attempt to Enter into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:		
☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):		
☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)		
REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____
Registrant's Name and Address: _____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: _____
(Signature)

Dated: _____
(Typed)

EPA Form 8580-3

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No. _____ Date _____

Guidance Document for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submit- ting Data (At- tached)	(For EPA Use Only) MRID Numbers Assigned
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk- density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No. _____ Date _____

Guidance Document for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number		Submit- ting Data (At- tached)	(For EPA Use Only) MRID Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)						
63-13	Stability					
63-14	Oxidizing/reducing reaction					
63-15	Flammability					
63-16	Explosibility					
63-17	Storage stability					
63-18	Viscosity					
63-19	Miscibility					
63-20	Corrosion characteristics					
63-21	Dielectric break- down voltage					
Sec. 158.340 TOXICOLOGY						
81-1	Acute oral toxicity, rat					
81-2	Acute dermal toxicity, rabbit					
81-3	Acute inhalation, toxicity, rat					
81-4	Primary eye irritation, rabbit					
81-5	Primary dermal irritation					
81-6	Dermal sensitiza- tion.					
81-7	Acute Delayed neurotoxicity, hen					

EPA Form 8580-4 (cont'd)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA		
(To qualify, certify <u>ALL</u> four items)		
1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:		GUIDANCE DOCUMENT DATE
		ACTIVE INGREDIENT
		EPA COMPANY NUMBER
(This firm or group of firms is referred to below as "my firm".)		
2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:		
3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):		
NAME OF FIRM		DATE OF OFFER
However, none of those firm(s) accepted my offer.		
4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.		
TYPED NAME	SIGNATURE	DATE